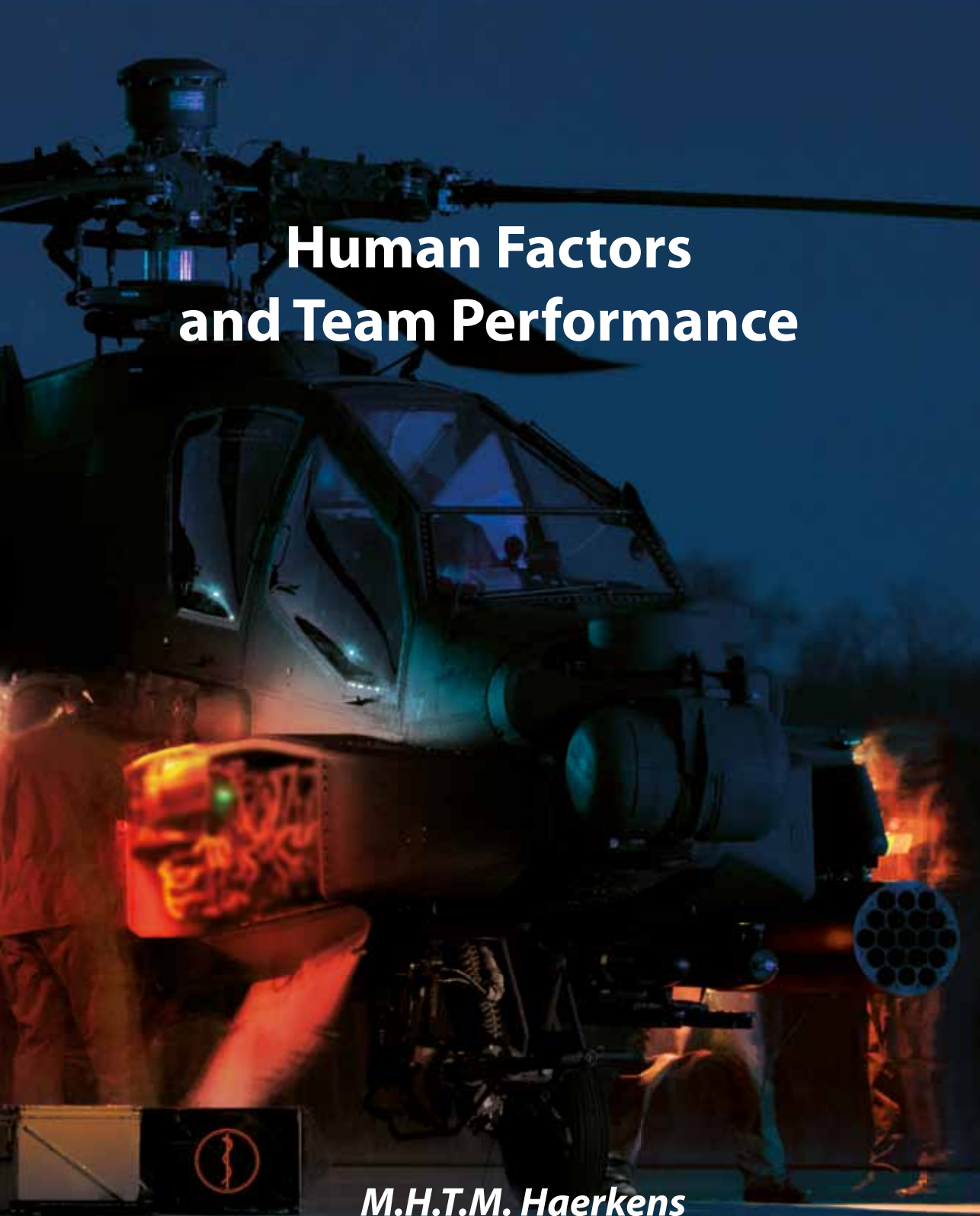
Human Factors and Team Performance



M.H.T.M. Haerkens

Human Factors and Team Performance

M.H.T.M. Haerkens

Colofon

The research presented in this thesis was performed at the Department of Intensive Care, Radboud University Nijmegen Medical Centre, the Netherlands.

Sponsoring of this thesis was kindly provided by:
- Department of Intensive Care Radboudumc
- Wings of Care

Cover design: Siegfried Woudstra
Photo's provided by: Jacob Woudstra
Lay out and print management: WoodyDesign

ISBN: 9789077245-66-8
NUR: 876

Human Factors and Team Performance

Proefschrift

ter verkrijging van de graad van doctor
aan de Radboud Universiteit Nijmegen
op gezag van de rector magnificus prof. dr. J.H.J.M. van Krieken,
volgens besluit van het college van decanen
in het openbaar te verdedigen op donderdag 19 januari 2017
om 10:30 uur precies

door

Marcus Henricus Theresia Maria Haerkens
geboren op 26 juni 1962
te Eindhoven

Promotoren
Prof. dr. J.G. van der Hoeven
Prof. dr. P. Pickkers

Copromotor
Dr. M. Kox

Manuscriptcommissie
Prof. dr. G.J. Scheffer
Prof. dr. G.P. Westert
Prof. dr. J.D. Kerby (University of Alabama at Birmingham, Verenigde Staten)

Contents

Chapter 4 Impact of CRM in the Intensive Care Unit

MHTM Haerkens, M Kox, J Lemson, S Houterman, JG van der Hoeven, P Pickkers:
Crew Resource Management in the Intensive Care Unit: a prospective 3-year cohort study.
Acta Anaesth Scand 2015; 59:10, 1319–1329

Chapter 5 Impact of CRM in the Trauma Room

MHTM Haerkens, PM Noe, M Kox, JG van der Hoeven, P Pickkers:
Crew Resource Management in the Trauma Room: a prospective three-year cohort study.
Provisionally accepted for publication in Eur J Emerg Med.

Chapter 6 Implementation experience and challenges

6.1 Implementation - a longitudinal study

Based on:

MHTM Haerkens, W van Leeuwen, M Kox, P Pickkers, JG van der Hoeven:
A Longitudinal Study on the Effect of Crew Resource Management on Safety Climate in Healthcare.
Submitted for publication.

6.2 Implementation - challenges

Based on:

MHTM Haerkens, CJ Lorraine, TC Oud, P Pickkers, JG van der Hoeven:
Implementation challenges of Crew Resource Management.
J ICU Management & Practice 2016; 16(2):88; 90-91

J Lemson, MHTM Haerkens:
Never waste an opportunity to debrief.
Crit Care Med 2014; 42:7, 1740-1741

Chapter 7 Summary and future perspectives

7.1 Summary

7.2 Future perspectives

Based on:

MHTM Haerkens:
Team aspects of Patient Safety.
Dutch Patient Safety Manual 2016; Part 5, Chapter 23.
ISBN: 9789058983060

ECTH Tan, MHTM Haerkens:
Crew Resource Management.
Acute Healthcare 2014; Chapter 1.4.
ISBN: 9789035236233

Chapter 8 Appendices

8.1 Summary in Dutch - Samenvatting

8.2 Publications

8.3 Acknowledgements - Dankwoord

8.4 Curriculum Vitae

Chapter 1

Introduction

1.1 Justus

Fourteen years ago, in the crew room of Royal Netherlands Air Force (RNLAF) 301 Squadron, fellow aviator "Spank" shared the story of his newborn son.

Justus arrived into this world prematurely, with a serious medical condition called gastroschizis. A vulnerable little patient in need of specialised care.

When Justus was transferred to a high-end, well-equipped Neonatal Intensive Care Unit, the parents encountered clinical staff with lots of individual knowledge and motivation.

But Justus was not doing well. And when complications occurred his parents grew increasingly anxious.

Spank, being aviator and flight safety officer, could not help noticing threats to safe care: suboptimal reaction to alarms, ineffective shift handovers, fragile interdisciplinary teamwork, and communication techniques nowhere near the Air Force standards he knew so well.

After sharing his observations with the doctor in charge, Spank provided information on the RNLAF's Human Factors awareness program entitled Crew Resource Management (CRM). This resulted in a request for an introductory CRM-course for the clinical team involved. Our very first effort to adapt aviation Human Factors principles to the hospital environment was well received by this medical team, who embrace the CRM principles to date.

Justus survived and has grown into a fine young man, doing very well at school. His proud parents hope that more of my fellow caregivers will learn from his story.

1.2 The scope of the problem

Medical care frequently results in unintentional harm to patients. Despite the best intentions of caregivers, technical advancements, quality and safety programs and ever more stringent procedural guidelines, statistics do not seem to improve. If medical error were a disease, it would rank as the third leading cause of death in the US.[1]

Human Factors

To err is human.[2] As a result everything that a human being devises, uses, or does is prone to error and failure. Human Factors (HF), also known as ergonomics, uses scientific methods to understand better human behavior in relation to organizational and task factors. The aim is to improve system performance and prevent accidental harm.[3]

In clinical medicine, HF-related errors can have a major impact on patient safety.[2,4] Especially in departments where high risk, time critical procedures on vulnerable patients are performed in a multidisciplinary team setting, HF are likely to play an important role.[5] This is for instance illustrated by the fact that the occurrence of complications is related to outcome in critically ill patients.[6,7]

Safety Climate

As HF account for the majority of adverse events, assessing the "safety culture" within a healthcare organization is considered important. While several definitions of the term "safety culture" exist, it may best be described as the shared values, beliefs and principles towards safety within an organization.[8]

Measuring safety culture is challenging and would require careful, long-term observations. Within the healthcare domain it may therefore be more appropriate to use the term "safety climate" (the daily practices and behaviors of individual healthcare professionals as well as interactions within and between healthcare teams), which can be determined by questionnaires.

Evidence from other critical industries suggests that safety climate correlates with unsafe and safety-specific behavior, injury rates and accidents.[9,10]

Crew Resource Management

In multiple safety-critical domains HF have been identified as playing a key role in adverse events.[11,12,13,14,15]

The first domain to adopt a comprehensive HF awareness program was aviation, which introduced a training for aircrew entitled 'Crew Resource Management' (CRM) in 1979 after a series of accidents in which HF were found to be the root cause.[16]

CRM can be characterized as 'a team format which makes optimum use of all available resources - time equipment, procedures and people - to enhance process safety and effectiveness'. The key aspect of CRM is a system approach to safety culture, focusing on 'threat and error management'. Rather than focusing on individual failure, CRM aims to identify system flaws and uses standardized communication tools to improve process effectiveness and safety.

Following the implementation of CRM, a decrease in adverse events led to CRM becoming the present day aviation operational standard, despite the lack of sound scientific proof of the impact of CRM on aviation safety outcome.[17] Meta-analyses of the effectiveness of CRM in aviation show positive reactions of course participants, enhanced learning, and desired behavioral changes.[18]

Also, other critical domains that implemented the CRM format report encouraging behavioural changes, but were also unable to provide conclusive evidence on process safety.[19,20,21]

The joint efforts of several aviation and maritime institutes (Dutch Maritime Pilots' Corporation, Finnish Maritime Administration, Norwegian Ship owners' Association, SAS Flight Academy, Silja Line, Swedish Maritime Administration, Swedish Ship owners' Association and The Swedish Club) resulted in the launch of Maritime Resource Management (MRM) in 1993.[22]

To investigate the effect of MRM implementation, the Swedish Club non-profit mutual insurer decided to compile all their navigational claims from 1998-2007. Star Cruises, which implemented MRM in the 90's, stood out. Despite operating in difficult and congested waters, and in sharp contrast to other merchant and cruise operators, Star Cruises had zero insurance claims for the eight ships that they operated in the ten year period. This performance has been maintained to date. While MRM training is currently available in over 30 countries worldwide, no uniform standard for maritime HF training has been agreed upon.

In the 90's CRM found its way into healthcare. As in the maritime environment a medical CRM training standard is still lacking, resulting in CRM-initiatives that vary in content, concept and quality of training. This variety is a challenging basis for comparing studies on healthcare CRM. While the parallels between the critical processes in aviation and medicine suggest that a well-adapted medical CRM format may have potential to improve patient safety, research efforts into the effects of CRM on professional behaviour and patient outcome yield an unsurprising myriad of results.
In their 2014 meta-analysis O'Dea et al. found that CRM training had large effects on participants' knowledge and behaviour, and a positive impact on teamwork in healthcare.[23]
After reviewing six studies Boet et al. concluded that CRM skills learned at the simulation centre are transferred to clinical settings, and the acquired CRM skills may translate to improved patient outcomes, including a decrease in mortality.[24]
In a large controlled study (74 facilities), Neilly et al. found that their Medical Team Training program was associated with lower surgical mortality.[25]
Kemper et al recently performed a robust paired controlled before-after study in six ICU's with one pretest and two post-test measurements after 3 and 12 months. In contrast to the aforementioned studies, it was concluded that their CRM implementation format did not change professional behaviour or patient outcomes. Whether these results were influenced by the relatively short follow-up period or the limited sample size remains unclear.[26]

Most studies do agree on the need for improved standardization of methods and measures, greater precision in outcome assessment, and more robust research design.

Thesis

This thesis reviews the existing literature on Human Factors awareness training, provides an open source safety climate assessment tool for the Netherlands, and reports on the implementation of Crew Resource Management in highly critical clinical environments.

References

1. Makary MA, Daniel M. *Medical error – the third leading cause of death in the US.* BMJ 2016; 353:i2139
2. Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system*. Washington: Institute of Medicine, National Academy Press, 2000
3. Russ AL, Fairbanks RJ, Karsh BT, Militello LG, Saleem JJ, Wears RL. *The science of human factors: separating fact from fiction.* BMJ Qual Saf 2013; 22:802–808
4. Brindley PG. *Patient safety and acute care medicine: lessons for the future, insights from the past.* Crit Care 2010;14:217
5. Garrouste-Orgeas M, Timsit JF, Vesin A, et al. *Selected medical errors in the intensive care unit: results of the IATROREF study: parts I and II.* Am J Respir Crit Care Med 2010; 181:134–42
6. Giraud T, Dhainaut JF, Vaxelaire JF, et al. *Iatrogenic complications in adult intensive care units: a prospective two-center study.* Crit Care Med 1993; 21:40–51
7. Haerkens MTHM, Kox M, Lemson J, et al. *Crew Resource Management in the Intensive Care Unit: a prospective 3-year cohort study.* Acta Anaesth Scand 2015; 59(10):1319-1329
8. Needle D. *Business in Context: An Introduction to Business and Its Environment*. Cengage Learning EMEA, 2004. ISBN 978-1861529923
9. Cooper MD, Phillips RA: *Exploratory analysis of the safety climate and safety behavior relationship.* J Saf Res 2004; 35:497–512
10. Nielsen KJ, Mikkelsen KL: *Predictive factors for self-reported occupational injuries at 3 manufacturing plants.* Saf Sci Monit 2007; 2:1–9
11. Nixon J, Leggatt A, Campbell J. *The development and assessment of behavioural markers to support counter-IED training.* Applied Ergonomics 2015; 48:130-137
12. Hagemann V, Kluge A. *The effects of a scientifically-based team resource management intervention for fire service teams.* Int J Human Factors and Ergonomics 2013; 2: Nos. 2/3
13. *The official report of The Fukushima Nuclear Accident Independent Investigation Commission*, English translation. The National Diet of Japan, 2012
14. *Final report and comments of the Netherlands Aviation Safety Board of the investigation into the accident with the collision of KLM Flight 4805, Boeing 747-206B, PH-BUF an Pan American Flight 1736, Boeing 747-121, N736PA at Tenerife Airport, Spain on 27 March 1977.* ICAO Circular 153-AN/56

15. Grech MR, Horberry, TJ, Koester T. *Human Factors in the Maritime Domain.* CRC Press 2008. pp. 130–132. ISBN 9781420043419
16. Cooper GE, White MD, Lauber JK. *Resource management on the flightdeck: proceedings of a NASA/industry workshop.* Moffett Field: NASA Ames Research Center, NASA CP-2120, 1980
17. Haerkens MHTM, Jenkins DH, van der Hoeven JG: *Crew Resource Management in the ICU: the need for culture change.* Ann Int Care 2012; 2:39
18. Salas E, Burke CS, Bowers CA, Wilson KA. *Team Training in the Skies: Does Crew Resource Management (CRM) Training Work?* Human Factors 2001; 43(4):641–674
19. Salas E, Wilson KA, Burke CS, Wightman DC. *Does Crew Resource Management Training Work? An Update, an Extension, and Some Critical Needs.* Human Factors 2006; 48(2):392–412
20. O'Connor P, Campbell J, Newon J, et al. *Crew resource management training effectiveness: A meta-analysis and some critical needs.* Int J Av Psych 2008; 18(4): 353-368
21. Griffith C, Roberts DL, Wakeham RT. *A Meta-Analysis of Crew Resource Management/Incident Command Systems Implementation Studies in the Fire and Emergency Services.* JAAER 2015; 25(1),1-25
22. Website: http://www.swedishclub.com/academy/maritime-resource-management-mrm/i
23. O'Dea A, O'Connor P, Keogh I. *A meta-analysis of the effectiveness of crew resource management in acute care domains.* Postgrad Med J 2014; 90(1070): 699-708
24. Boet S, Bould MD, Fung L, et al. *Transfer of learning and patient outcome in simulated crisis resource management: a systematic review.* Can J Anesth/J Can Anesth 2014; 61:571–582
25. Neily J, Mills PD, Young-Xu Y, et al. *Association Between Implementation of a Medical Team Training Program and Surgical Mortality.* JAMA 2010; 304(15):1693-1700
26. Kemper PF, de Bruijne M, van Dyck C, et al. BMJ Qual Saf 2016; 0:1–11

1.3 Outline

Medical care frequently results in unintentional harm to patients. In **chapter one** we discuss patient safety from a Human Factors perspective, and introduce the concept of Crew Resource Management (CRM).

Based on the Safety Attitudes Questionnaire (SAQ) benchmarked by Sexton et al. we developed and validated the SAQ-NL, an open-source instrument to measure safety climate for the Dutch clinical setting, The results are discussed in **chapter two**.

Next, we adapted the aviation-derived CRM Human Factors awareness training curriculum to the clinical environment and conceived a three-phased structure for CRM interventions. Both instruments are discussed in **chapter three**.

To determine whether implementation of CRM impacts outcome in critically ill patients and safety climate we conducted a study in the Intensive Care Unit to determine the effects of our CRM-intervention on ICU complication rates, ICU and hospital length of stay, standardized mortality ratio and safety climate (measured using the SAQ-NL). The results are described in **chapter four**.

Chapter five describes the effects of a CRM-intervention in the Trauma Room setting of an Emergency Department (ED). Outcomes were safety climate (again measured using the SAQ-NL), ED and hospital length-of-stay, and 48-hour crude mortality of trauma patients.

Experience from CRM integration projects in 19 high-risk clinical departments has helped us identify several key success factors as well as threats to success that may be of use to future clinical CRM initiatives. **Chapter six** provides a longitudinal multicenter study into the impact of CRM on safety

climate, and identifies factors for successful implementation insight on an operational as well as managerial level.

Finally, **chapter seven** summarizes the results of the studies and discusses current issues and future perspectives.

Chapter 2

Validation of the Dutch language version of the Safety Attitudes Questionnaire (SAQ-NL).

MHTM Haerkens
W van Leeuwen
JB Sexton
P Pickkers
JG van der Hoeven

BMC Health Services Research 2016; 16:385

Abstract

Background

As the first objective of caring for patients is to do no harm, patient safety is a priority in delivering clinical care. An essential component of safe care in a clinical department is its safety climate. Safety climate correlates with safety-specific behaviour, injury rates, and accidents. Safety climate in healthcare can be assessed by the Safety Attitudes Questionnaire (SAQ), which provides insight by scoring six dimensions: Teamwork Climate, Job Satisfaction, Safety Climate, Stress Recognition, Working Conditions and Percep-tions of Management.

The objective of this study was to assess the psychometric properties of the Dutch language version of the SAQ in a variety of clinical departments in Dutch hospitals.

Methods

The Dutch version (SAQ-NL) of the SAQ was back translated, and analyzed for semantic characteristics and content. From October 2010 to November 2015 SAQ-NL surveys were carried out in 17 departments in two university and seven large non-university teaching hospitals in the Netherlands, prior to a Crew Resource Management human factors intervention. Statistical analyses were used to examine response patterns, mean scores, correlations, internal consistency reliability and model fit. Cronbach's α's and inter-item correlations were calculated to examine internal consistency reliability.

Results

1314 completed questionnaires were returned from 2113 administered to health care workers, resulting in a response rate of 62%. Confirmatory Factor Analysis revealed the 6-factor structure fit the data adequately. Response patterns were similar for professional positions, departments, physicians and nurses, and university and non-university teaching hospitals. The SAQ-NL showed strong internal consistency (α = .87). Exploratory analysis revealed

differences in scores on the SAQ dimensions when comparing different professional positions, when comparing physicians to nurses and when comparing university to non-university hospitals.

Conclusions
The SAQ-NL demonstrated good psychometric properties and is therefore a useful instrument to measure patient safety climate in Dutch clinical work settings. As removal of one item resulted in an increased reliability of the Working Conditions dimension, revision or deletion of this item should be considered. The results from this study provide researchers and practitioners with insight into safety climate in a variety of departments and functional positions in Dutch hospitals.

Keywords
Human Factors, Crew Resource Management (CRM), Safety Attitudes Questionnaire (SAQ), Dutch hospital setting

Background

To err is human. As a result, everything that a human being devises, uses, or does is prone to error and failure. As this challenges the "First: do no harm" principle of healthcare[1], it is imperative to assess the factors that impact patient safety.
Patient safety is regarded by the National Patient Safety Foundation as the avoidance, prevention, and amelioration of adverse events or injuries stemming from the processes of healthcare.[2] Identifying the key factors in safe clinical care is a challenging task.

Evidence from non-clinical[3] and clinical[4-8] critical environments suggests a positive relationship between safety culture, safety climate, and safety outcome. Safety culture is defined by the British Health & Safety Commission as "the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's safety management.[9] From an anthropological standpoint, "safety culture" is only measurable by careful, long-term observations. Therefore, in daily clinical practice, it may be more appropriate to use the term "safety climate", which generally refers to the measurable components of safety culture such as management behaviors, safety systems, and employee perceptions of safety.
Safety climate can be determined by the Safety Attitudes Questionnaire (SAQ), a validated healthcare derivative of the Cockpit Management Attitudes Questionnaire[10] that has been adapted to various clinical settings.[4, 11] The initial extended version consists of 60 items including 30 core items that are identical in all clinical settings. The short form version includes only the 30 core items.
Previous factor analysis identified factors covering six domains of the safety climate: *Teamwork Climate* (6 items) is the perceived quality of collaboration between personnel. *Job Satisfaction* (5 items) is defined as positivity about the work experience. *Safety Climate* (7 items) is the perception of a strong and proactive organizational commitment to safety. *Stress Recognition*

(4 items) is acknowledgement of how performance is influenced by stressors. *Working Conditions* (3 items) is the perceived quality of the work environment and logistical support (such as staffing and equipment). *Perceptions Of Management* (5 items) is the approval of managerial action.[10] SAQ responses are given on a 5-point Likert scale (1 = disagree strongly, 2 = disagree slightly, 3 = neutral, 4 = agree slightly, 5 = agree strongly). Two items (items 2,11) are reversed scored.[12]

Although the SAQ has been utilized in safety research in the Dutch care setting[6, 13, 14], no open source Dutch language version of the SAQ has been published to date. One exception is the observational study on the content validity and internal consistency of a Dutch translation of the SAQ by Devriendt and colleagues which was published during the course of our study.[15] Although good content validity (CVI = .83) and internal consistency (α = .90) were reported, the sample in the study was limited to, and conducted in, a single hospital in the culturally different context of Belgium.[15] Furthermore, even though Belgium and the Netherlands are neighboring countries the Dutch language differs from the Belgian-Dutch language (Flemish), which is clearly visible in the Belgian-Dutch questions. Contrary to our study, no certified interpreters and/or native English speakers performed the translation and the adapted Brislin protocol of forward and back translation was not used.

The Dutch hospital system consists of three levels of hospitals: large university hospitals, medium size non-university training hospitals and smaller rural hospitals.

The aim of the current study was to assess the psychometric properties of the Dutch language version of the SAQ (SAQ-NL) and provide insight into safety climate in a variety of departments and functional positions in Dutch hospitals.

Background

Design and setting

From October 1st 2010 to November 1st 2015 a cross-sectional survey was conducted in 17 departments in two university and seven non-university teaching hospitals in the Netherlands as part of an intervention study evaluating the impact of Crew Resource Management (CRM) – human factors awareness training. This study focuses on the baseline data gathered before the CRM-training.

The clinical departments (and number of health care providers) that participated in this study included: two Intensive Care Units (ICU, n = 281), five Operating Rooms (OR, n = 648), two Cardiac Catheterization Labs (CCL, n = 56), one Medium Care Unit (MCU, n = 33), three Emergency Rooms (ER, n = 163), one Coronary Care Unit - Heart First Aid unit (CCU-HFA, n = 45), one Radiotherapy department (RTX, n = 12), one Department of Gastroenterology and Hepatology (DGH, n = 40) and one Pharmacy department (n = 36).

The Safety Attitudes Questionnaire - NL

It was decided to use the original 30-item version of the SAQ benchmarked by Sexton et al.[10, 16] containing identical questions for all clinical settings as the basis for the Dutch version because of its usability in multiple clinical environments, good psychometric properties and open source accessibility.

When introducing a foreign language questionnaire, potential semantic and cultural differences need to be taken into account. To determine semantic equivalence (the translated items have the same meaning as in the original) in the translated version the SAQ was translated from English to Dutch and back again by native speakers (of which one is a certified interpreter) following the adapted Brislin protocol.[17,18] The translated version was reviewed for semantic properties and content. A subject matter experts group, consisting of clinical faculty (n = 3), psychologists (n = 2) and human factors specialists (n = 3), analyzed clarity and appropriateness of wording and each item's meaning in the cultural setting of the Netherlands.

Data collection

All professionals of each participating department received an invitation to fill out the SAQ-NL. The first five departments were issued a paper and pencil version, all participants in subsequent departments received a link to an online questionnaire. There was no significant difference between the groups associated with method of administration.

Statistical analysis

Frequency tables were generated to provide an overview of age categories, gender, professional positions, departments, department tenure, and hospital tenure of the responders. To provide an overview of response patterns, percentages for missing values (MV) were generated. Further analysis of MV was done by first recoding all MV to '0' and all responses to '1'. These recoded values were then aggregated to yield an overall response score.

A univariate analysis of variance (ANOVA) was performed with the overall response score as dependent variable and profession and department as independent variables to check for differences in the overall response score. Independent t-tests were applied to compare the overall response scores between university and non-university hospitals and between medical staff (attending physicians and residents) and support personnel (nurses, operating room assistants, and operating room assistants). Mean scores were calculated per item and then aggregated to yield a mean score per SAQ dimension. Furthermore, to provide an overview of percentages of participants that agreed or disagreed with an item, responses of 1 and 2 on the 5-point scale were recoded as 'disagree' and responses 4 and 5 were recoded as 'agree'.

Scale reliability analyses with all items and for each dimension separately resulted in a corrected item-total correlation and a Cronbach's α if an item is deleted for the dimension-scale. An overview of missing values, means and standard deviations, percentages agree and disagree, corrected item-total correlations, Cronbach's α's, and Cronbach's α's if an item is deleted were calculated.

Based on the results of the factor analysis as performed earlier[10], a confirmatory factor analysis (CFA) was performed on participants who fully completed the instrument (n = 604). CFA was performed with analysis of moment structures (AMOS) software[19].

We deemed a successful model was that with a Goodness of Fit Index (GFI) > 0.9[20], a Comparative Fit Index close to 0.95[21] and a Root Mean Square Error of Approximation (RMSEA) < 0.08[22]. The χ^2 statistic is also given (a poor measure of model fit of measurement, but included here for reasons of convention).

The unrestricted model was based on the structure of the original database. We fit a six factor unrestricted CFA model that contained the 30 items retained in the previous study of Sexton et al[10] that confirmed the SAQ's construct validity.

Mean scores and standard deviations for each SAQ-NL dimension were calculated for professional positions, physicians (residents and attending physicians) vs. nurses, departments, and academic status separately. Note that the category 'nurses' consists of nurses, operating room technicians, and anaesthesiology technicians. To explore whether groups differed on mean scores, multivariate analysis of variance (MANOVA) was utilized to interpret the mean scores. Because SPSS removes all participants with missing values in any combination of more than one independent variable, three separate MANOVA's were performed with professional position, physicians vs. nurses, and university status of the hospital as independent variables and the mean scores on each dimension as dependent variables. Because dependent variables were not highly correlated and because it is robust to many violations of MANOVA, Pillai's trace was utilized as the MANOVA test statistic.[23]

Since no a priori hypotheses were formulated, a post-hoc Bonferroni test was utilized to interpret significant findings when the independent variable consisted of more than two groups. Finally, a bivariate correlation analysis was done to provide an overview of relations between SAQ-NL dimensions. For the correlation analysis, Pearson's correlation was used with a two-tailed test of significance.

Because of the large statistical power due to large sample size, corresponding effect sizes are reported to interpret significant findings. The following cut-offs were used: small effect (Cohen's d = 0.2, $\eta_p^2 = 0.01$), medium effect (d = 0.5, $\eta_p^2 = 0.06$), large effect (d = 0.8, $\eta_p^2 = 0.14$). Data was analysed using SPSS Statistics 22 (IBM Corp., Armonk, NY, USA). A p-value < 0.05 was considered to indicate significance.

Results

Demographics

1314 of 2113 surveys were returned for a response rate of 62%. This final sample consisted of 623 nurses (47%), 239 attending physicians (18%), 90 residents (6.8%) and 214 "category other" (16%). A total of 148 participants (11%) did not provide their position details. The university hospitals (n = 2) employed 441 respondents, 873 respondents were employed by non-university teaching hospitals (n = 7). The database contained one outlier department with an exceptionally low response rate of 21%.

Detailed demographic and professional characteristics of the responders are shown in Table 1.

SAQ-NL factor structure and multi-level modeling

The SAQ-NL with six factors and 30 items was used in all the administrations reported here. The 6-factor model fit the data well: $\chi^2(390) = 931.18$, $p < 0.001$, GFI = 0.90, CFI = 0.91, and RMSEA = 0.05. Item loadings on respective factors appear in Table 4.

SAQ-NL item characteristics

The subject matter experts adjusted the items until they agreed on the appropriateness of the semantic characteristics and deemed the content sufficient and appropriate for measuring safety climate in hospitals. Missing values (MV) analysis revealed a range of 3.0 - 6.8% MV for the separate questions, see Table 4. ANOVA revealed no difference in MV for professional position, F(3, 1110) = 0.02, p = .996, or department, F(7, 1110)

= 1.23, p = 0.283. Independent t-tests revealed no difference in MV for university status, t(1283.83) = 1.83, p = 0.059, and physicians vs. nurses t(950) = 0.75, p = 0.452. Due to a technical error, item 16 ("this is a good place to work") did not appear in the questionnaire initially and therefore resulted in a MV of 50%.

SAQ-NL mean scores

An overview of mean scores and standard deviations for comparison is provided in Table 2. Using Pillai's trace, the overall MANOVA's revealed a medium effect of clinical position (n = 1159), V = 0.19, F(18, 3456) = 13.25, $p < 0.001$, $\eta_p^2 = 0.07$, a large effect of physicians vs. nurses (n = 947), V = 0.14, F(6, 940) = 26.37, $p < 0.001$, $\eta_p^2 = 0.14$, and a small effect of academic status of the hospital (n = 1257), V = 0.03, F(6, 1250) = 6.65, $p < 0.001$, $\eta_p^2 = 0.03$, on the six SAQ-NL dimensions; Teamwork Climate, Safety Climate, Job Satisfaction, Stress Recognition, Perceptions of Management, and Working Conditions. Follow-up univariate ANOVA's revealed that there was an effect of professional position on Teamwork Climate, F(3, 1155) = 49.08, $p < 0.001$, $\eta_p^2 = 0.11$, on Safety Climate, F(3, 1155) = 22.63, $p < 0.001$, $\eta_p^2 = 0.06$, on Job Satisfaction, F(3, 1155) = 23.69, $p < 0.001$, $\eta_p^2 = 0.06$, on Perceptions of Management, F(3, 1155) = 2.95, p = .032, $\eta_p^2 = 0.01$, and on Working Conditions, F(3, 1155) = 13.63, $p < 0.001$, $\eta_p^2 = 0.03$. An overview of means and confidence intervals is provided in Figure 1.

A post-hoc Bonferroni test revealed that attending physicians were more positive about Teamwork Climate than both residents, $p < 0.001$, d = 0.35, and nurses, $p < 0.001$, d = 0.90. Residents were more positive about Teamwork Climate than nurses, $p < 0.001$, d = 0.59. For Safety Climate, attending physicians were more positive than residents, p = 0.008, d = 0.06, and nurses, $p < 0.001$, d= 0.64. Furthermore, nurses experienced lower Job Satisfaction than attending physicians, $p < 0.001$, d = 0.59, and residents, p = 0.001, d = 0.47. Finally, nurses were less positive about Working Conditions than attending physicians, $p < 0.001$, d = 0.42, and residents, p = 0.001, d = 0.46.

The follow-up univariate ANOVA's concerning physicians vs. nurses revealed that physicians were more positive about Teamwork Climate than nurses, $F(1, 945) = 111.90$, $p < 0.001$, $\eta_p^2 = 0.12$. Physicians were more positive about Safety Climate than nurses, $F(1, 945) = 60.43$, $p < 0.001$, $\eta_p^2 = 0.06$. Physicians experienced more Job Satisfaction than nurses, $F(1, 945) = 65.23$, $p < 0.001$, $\eta_p^2 = 0.07$. Physicians had higher Perceptions of Management than nurses, $F(1, 945) = 4.73$, $p = 0.030$, $\eta_p^2 = 0.01$. Finally, physicians were found to experience better Working Conditions than nurses, $F(1, 945) = 30.12$, $p < 0.001$, $\eta_p^2 = 0.04$. An overview of means and confidence intervals is provided in Figure 2.

Follow-up univariate ANOVA's related to university status of the hospital revealed that university hospitals were more positive about Teamwork Climate than teaching hospitals, $F(1, 1255) = 6.23$, $p = 0.013$, $\eta_p^2 = 0.01$. Also, more Job Satisfaction was experienced in university hospitals than in teaching hospitals, $F(1, 1255) = 7.28$, $p = 0.007$, $\eta_p^2 = 0.01$. Scores on Stress Recognition were lower in academic hospitals than in teaching hospitals, $F(1, 1255) = 6.91$, $p= 0.009$, $\eta_p^2 = 0.01$. In university hospitals, Perceptions of Management were higher than in teaching hospitals, $F(1, 1255) = 33.54$, $p < 0.001$, $\eta_p^2 = 0.03$. Finally, university health care providers from hospitals were more positive about Working Conditions than teaching hospitals, $F(1, 1255) = 9.58$, $p = 0.002$, $\eta_p^2= 0.01$. An overview of means and confidence intervals is provided in Figure 3.

Reliability and correlation analysis

Reliability analysis of the SAQ-NL showed strong internal consistency, Cronbach's $\alpha = .87$, see Table 4. For the Perceptions of Management and Working Conditions categories Cronbach's α's were below the .70 reliability threshold (.65 and .57, respectively) though. Interestingly, in spite of having no effect on overall SAQ-NL reliability, exclusion of item 29 would result in the Working Conditions dimension reliability increasing from .57 to .70.

Teamwork Climate and Safety Climate were correlated at about .70. In addition, Stress Recognition was consistently negatively related to all other categories (see Table 3).

Discussion

We developed and refined a Dutch language version of the SAQ and used it on a broad sample of hospital departments in the Netherlands. CFA confirmed the appropriateness of the proposed model and the resulting psychometric properties were good for this instrument. Internal consistency as well as correlations were similar to the results published by Sexton and colleagues (2006) in their validation study of the SAQ.[10]

Furthermore, reference data were reported for comparison purposes. In a pattern of results quite similar to what has been found in other translations of the SAQ[16, 24], the SAQ-NL was associated with significant unit-level variability, higher scores for physicians than non-physicians, and psychometrically valid scales.

Explorative analyses of the data revealed two interesting findings. First, the robust finding that physicians score higher in 5 out of 6 SAQ-NL domains than nurses is consistent with previous research.[25] This represents a different perception of the safety climate within clinical teams, a factor that should be taken into account during human factors awareness training. Second, university hospitals were found to be slightly more positive about safety climate than non-university teaching hospitals. A possible explanation might be the lower clinical production pressure perceived in the academic setting, as well as a teaching environment with more emphasis on supervision. However, university hospitals scored slightly lower in stress recognition. We can offer no explanation for this finding. Several studies find that the SAQ-factor Stress Recognition has problems regarding construct validity and that it does not vary significantly between organizational units[26].

Strengths

The first strength of the present study is the broad spectrum of participating hospitals, departments and professionals resulting in a sample that could be considered a representative cross section of acute and critical care departments in the Dutch clinical healthcare setting. In addition, the large

sample size resulted in sufficient representation of professionals in the categories utilized in this study. Thirdly, as this study provides an open source Dutch translation of the SAQ short form, it may serve as a basis for future research. This would allow for better comparison of future investigations into safety climate in hospital departments in the Netherlands.

Limitations

The most important limitation of the present study is the fact that hospital departments were not a random sample. The SAQ-NL was determined in units that were to receive human factors training, and it is therefore possible that these non-random units had safety culture norms that were not representative. One could argue that the fact that they signed up for human factors training could be the result of priority given to safety climate resulting in a higher safety culture norm than expected, or the opposite, that these departments wished to participate because of perceived problems with safety. A brief comparison of our overall means to other samples suggests that the latter was not the case. Nevertheless this would not impact the psychometric results, which ranged from adequate to good. Second, in spite of our efforts to include as many different departments and clinical specialties as possible, we recognize this study cannot encompass the total clinical spectrum. We therefore encourage further research covering even more clinical specialties inside and outside of inpatient settings.

Third, item 16 ("this is a good place to work") did not appear in the questionnaire initially and therefore resulted in a MV of 50%. However, the large sample size limits the impact of this omission.

Finally, this study period covered 5 years. Possible effects of general changes in perceptions of clinical safety climate during this timeframe cannot be excluded. Nevertheless, results from the first two years compared to the last two years did not yield significant differences (data not shown), indicating that this is not likely to be an issue.

Perceived safety climate is associated with safety outcomes in hospital settings.[27] Therefore, determination of safety climate is of clinical relevance. The SAQ-NL in its present form shows promise to be a benchmarked tool for future research into patient safety. Exclusion of item 29 "All the necessary information for diagnostic and therapeutic decisions is routinely available to me" would result in an increase of Working Conditions dimension reliability (from .57 to .70). Even though this would not impact overall SAQ-NL reliability, adapting, deleting, or at the very least, monitoring this item is something to consider in future research that utilizes the SAQ-NL. After this adjustment psychometric properties should be reassessed in a randomly selected sample and hospitals and departments prior to more widespread use in Dutch hospital settings.

Conclusions

We assessed the psychometric properties of the Dutch language version of the SAQ, the SAQ-NL, and provided insight into safety climate in a variety of clinical departments in Dutch hospitals. The SAQ-NL is a reliable instrument to measure safety climate in the Dutch hospital setting. Further research is needed to validate the SAQ-NL as a monitoring tool for pre-and-post administration of the impact of interventions related to safety climate.

List of abbreviations

AMOS	Analysis of MOment Structures
ANOVA	Univariate analysis of variance
CFA	Confirmatory Factor Analysis
SAQ	Safety Attitudes Questionnaire
SAQ-NL	Dutch language version of the SAQ
CRM	Crew Resource Management
ICU	Intensive Care Unit
OR	Operating Room
CCL	Cardiac Catheterization Lab
MCU	Medium Care Unit
ER	Emergency Room
CCU-HFA	Coronary Care Unit - Heart First Aid unit
RTX	Radiotherapy
DGH	Department of Gastroenterology and Hepatology

Acknowledgements

The authors would like to thank interpreters Chris and Carol Lorraine for their translation efforts and essential feedback, Erik Lely for his support in extracting data from the SAQ-NL database as well as Esther van Lieshout for her advanced statistical input on short notice.

References

1. Inman T, Hayes I: *Book review of Foundation for a New Theory and Practice of Medicine*. The American Journal of the Medical Sciences 1860:450–458.
2. Cooper JB, Gaba DM, Liang B, Woods D, Blum LN: *The National Patient Safety Foundation agenda for research and development in patient safety*. MedGenMed 2000; 2(3):E38.
3. Cooper MD, Phillips RA: *Exploratory analysis of the safety climate and safety behavior relationship*. J Safety Res 2004; 35(5):497-512.
4. Huang DT, Clermont G, Kong L, Weissfeld LA, Sexton JB, Rowan KM, Angus DC: *Intensive care unit safety culture and outcomes: a US multicenter study*. Int J Qual Health Care 2010; 22(3):151-161.
5. Valentin A, Schiffinger M, Steyrer J, Huber C, Strunk G: *Safety climate reduces medication and dislodgement errors in routine intensive care practice*. Intensive Care Med 2013; 39(3):391-398.
6. Haerkens MH, Jenkins DH, van der Hoeven JG: *Crew resource management in the ICU: the need for culture change*. Ann Intensive Care 2012; 2(1):39.
7. Katz-Navon T, Naveh E, Stern Z: *Safety Climate in Healthcare Organizations: A Multidimensional Approach*. Academy of Management Journal 2005; 48:1075-1089.
8. Singer S, Lin S, Falwell A, Gaba D, Baker L: *Relationship of safety climate and safety performance in hospitals*. Health Serv Res 2009, 44(2 Pt 1):399-421.
9. Health and Safety Commission AHFSG: *Third Report: Organising for Safety*. 1993.
10. Sexton JB, Helmreich RL, Neilands TB, Rowan K, Vella K, Boyden J, Roberts PR, Thomas EJ: *The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research*. BMC health services research 2006; 6:44.
11. Helmreich RL: *Cockpit management attitudes. Hum Factors* 1984; 26(5):583-589.
12. Website: https://med.uth.edu/chqs/surveys/safety-attitudes-and-safety-climate-questionnaire/.
13. Poley MJ, van der Starre C, van den Bos A, van Dijk M, Tibboel D: *Patient safety culture in a Dutch pediatric surgical intensive care unit: an evaluation using the Safety Attitudes Questionnaire*. Pediatr Crit Care Med 2011; 12(6):e310-316.
14. Haerkens MH, Kox M, Lemson J, Houterman S, van der Hoeven JG, Pickkers P: *Crew Resource Management in the Intensive Care Unit: a prospective 3-year cohort study*. Acta Anaesthesiol Scand 2015; 59(10):1319-1329.

15. Devriendt E, Van den Heede K, Coussement J, Dejaeger E, Surmont K, Heylen D, Schwendimann R, Sexton B, Wellens NI, Boonen S et al: *Content validity and internal consistency of the Dutch translation of the Safety Attitudes Questionnaire: an observational study.* International journal of nursing studies 2012; 49(3):327-337.
16. Zimmermann N, Kung K, Sereika SM, Engberg S, Sexton B, Schwendimann R: *Assessing the Safety Attitudes Questionnaire (SAQ), German language version in Swiss university hospitals - a validation study.* BMC health services research 2013; 13:347.
17. Brislin RW: *The wording and translation of research instruments.* in: WJ Lonner, JW Berry (Eds) *Field methods in cross-cultural research,* Sage Publications, Newbury Park, CA 1986:137–164.
18. Jones PS, Lee JW, Phillips LR, Zhang XE, Jaceldo KB: *An adaptation of Brislin's translation model for cross-cultural research.* Nurs Res 2001; 50(5):300-304.
19. Arbuckle JL: *Amos* (Version 23.0) [Computer Program]. Chicago: IBM SPSS. 2014.
20. Shevlina M, Miles JNV: *Effects of sample size, model specification and factor loadings on the GFI in confirmatory factor analysis.* Personal Individ Differ 1998; 25(1):85–90.
21. Hu LT, Bentler PM: *Cutoff Criteria for Fit Indexes in Covariance Structure Analysis: Conventional Criteria versus New Alternatives.* Structural Equation Modeling 1998; 6(1):1-55.
22. MacCallum RC, Browne MW, Sugawara HM: *Power analysis and determination of sample size for covariance structure modeling.* Psychol Methods 1996; 1(2):130–149.
23. Warne RT: *A Primer on Multivariate Analysis of Variance (MANOVA) for Behavioral Scientists.* Practical Assessment, Research & Evaluation 2014; 19(17).
24. Deilkas ET, Hofoss D: *Psychometric properties of the Norwegian version of the Safety Attitudes Questionnaire (SAQ),* Generic version (Short Form 2006). BMC health services research 2008; 8:191.
25. Makary MA, Sexton JB, Freischlag JA, Holzmueller CG, Millman EA, Rowen L, Pronovost PJ: *Operating room teamwork among physicians and nurses: teamwork in the eye of the beholder.* J Am Coll Surg 2006; 202(5):746-752.

26. Bondevik GT, Hofoss D, Hansen EH, Deilkas EC: *The safety attitudes questionnaire - ambulatory version: psychometric properties of the Norwegian translated version for the primary care setting.* BMC health services research 2014; 14:139.
27. Sexton JB, Berenholtz SM, Goeschel CA, Watson SR, Holzmueller CG, Thompson DA, Hyzy RC, Marsteller JA, Schumacher K, Pronovost PJ: *Assessing and improving safety climate in a large cohort of intensive care units.* Crit Care Med 2011; 39(5):934-939.
28. Website: http://www.ccmo.nl/en/your-research-does-it-fall-under-the-wmo.

Figures

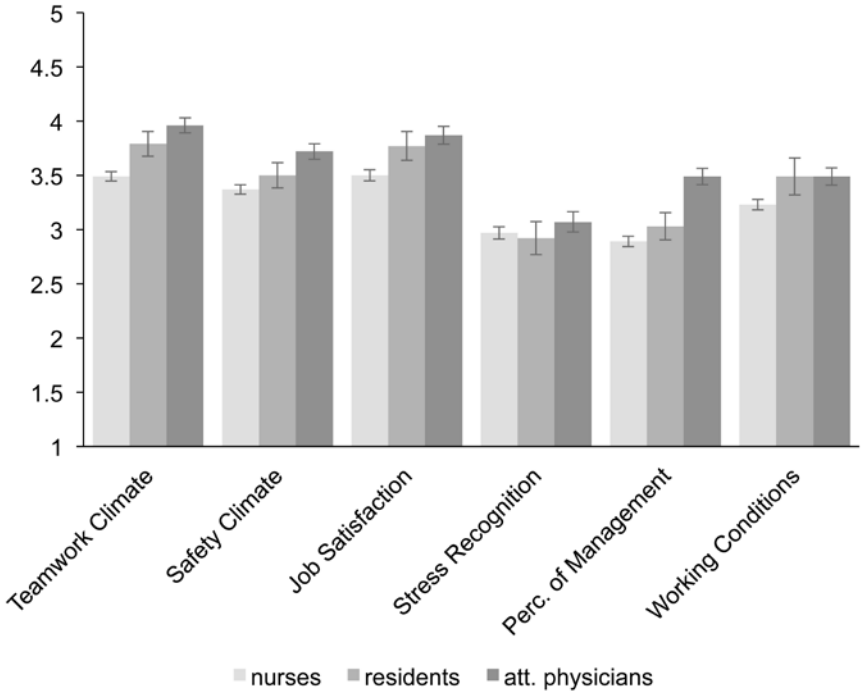


Figure 1

SAQ Means for Professional Position. Overview of mean scores and 95% Confidence Intervals.

Att. physicians = attending physicians; Perc. of Management = Perceptions of Management.

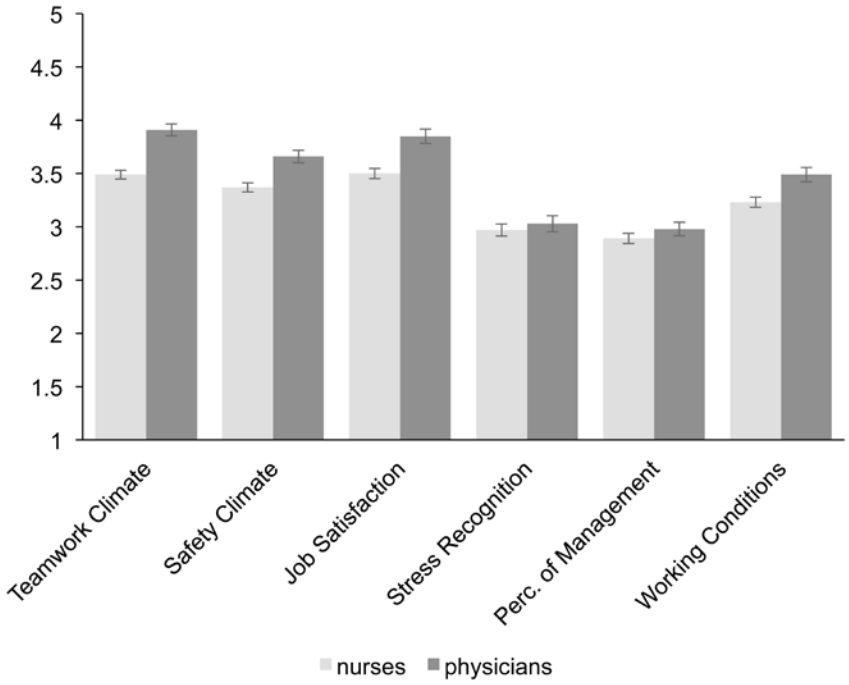


Figure 2

SAQ Means for Physicians versus Nurses. Overview of mean scores and 95% Confidence Intervals.

Perc. of Management = Perceptions of Management.

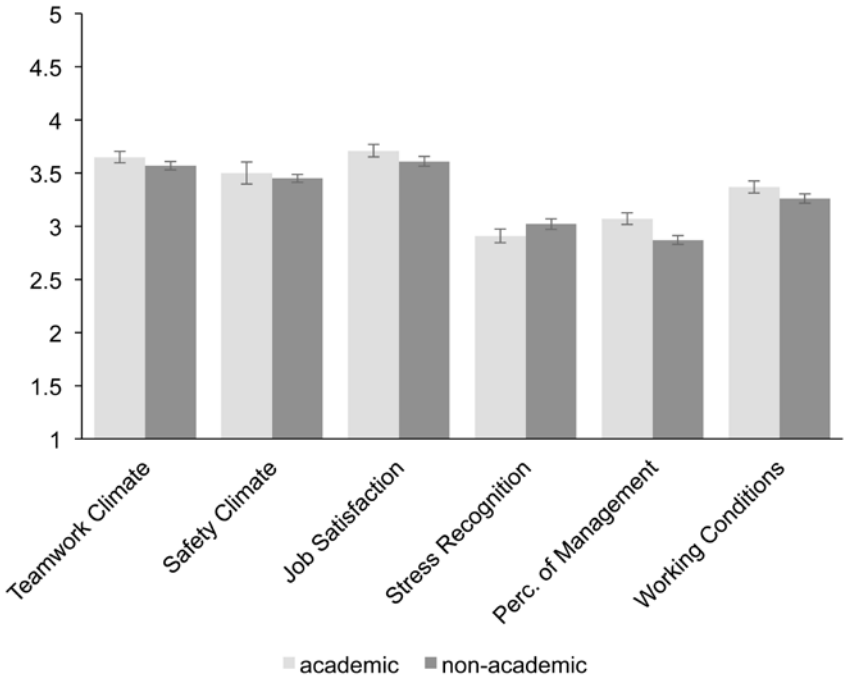


Figure 3

SAQ Means for Academic Status. Overview of mean scores and 95% Confidence Intervals.

Perc. of Management = Perceptions of Management.

Table 1

Frequency Table for Participant Demographic Variables, Departments, and Tenure

Age[a]		Gender		Position		Department		Tenure at department[a]		Tenure at hospital[a]	
Cat.	Freq. (%)	Cat.	Freq. (%)	Cat.	Freq. (%)		Freq. (%)	Cat.	Freq (%)	Cat.	Freq. (%)
≤ 20	25 (1.9)	Male	400 (30.4)	Nurse[b]	623 (47.4)	Intensive care	281 (21.4)	< 1	122 (9.3)	< 1	86 (6.5)
21 - 30	210 (16.0)	Female	813 (61.9)	Resident	90 (6.8)	Operating room	648 (49.3)	1 - 5	382 (29.1)	1 - 5	304 (23.1)
31 - 40	322 (24.5)			Att. physician	239 (18.2)	CCL	56 (4.3)	6 - 10	243 (18.5)	6 - 10	237 (18.0)
41 - 50	365 (27.8)			Other	214 (16.3)	Medium care	33 (2.5)	> 10	476 (36.2)	> 10	596 (45.4)
> 50	304 (23.1)					Emergency room	163 (12.4)				
						CCU - HFA	45 (3.4)				
						Radiotherapy	12 (0.9)				
						DGH	40 (3.0)				
						Pharmacy	36 (2.7)				
Missing	88 (6.7)		101 (7.7)		148 (11.3)		0		91 (6.9)		91 (6.9)

Note. *N* = 1314; Cat. = Category; Freq. = Frequency; Att. physician = Attending physician; CCL = Cardiac Catheterization Lab; CCU-HFA = Coronary Care Unit - Heart First Aid unit; DGH = Department of Gastroenterology and Hepatology; [a] Age and tenure in years; [b] Nurse category consists of nurses, operating room technicians, and anaesthesiology technicians.

Table 2

SAQ-NL Means and (Standard Deviations) per Professional Position and Department

	Teamwork Climate	Safety Climate	Job Satisfaction	Stress Recognition	Perc. of Management	Working Conditions
Position						
Nurse	3.49 (0.55)*	3.37 (0.52)*	3.50 (0.64)*	2.97 (0.70)	2.89 (0.60)	3.23 (0.61)*
Resident	3.79 (0.47)*	3.50 (0.50)*	3.77 (0.51)*	2.92 (0.72)	3.03 (0.53)	3.49 (0.53)*
Attending physician	3.96 (0.49)*	3.72 (0.58)*	3.87 (0.62)*	3.07 (0.74)	2.96 (0.62)	3.49 (0.63)*
Other	3.47 (0.64)	3.52 (0.64)	3.75 (0.70)	2.98 (0.82)	3.01 (0.62)	3.24 (0.71)
Physician vs Nurse						
Physicians	3.91 (0.49)*	3.66 (0.57)*	3.85 (0.59)*	3.03 (0.73)	2.98 (0.60)*	3.49 (0.60)*
Nurses	3.49 (0.55)*	3.37 (0.52)*	3.50 (0.64)*	2.97 (0.70)	2.89 (0.60)*	3.23 (0.61)*
Department						
Intensive care	3.74 (0.47)	3.50 (0.44)	3.72 (0.49)	2.95 (0.60)	3.07 (0.51)	3.36 (0.52)
Operating room	3.48 (0.60)	3.41 (0.61)	3.48 (0.71)	3.00 (0.74)	2.84 (0.62)	3.28 (0.65)
CCL	3.76 (0.53)	3.71 (0.53)	4.01 (0.53)	2.79 (0.72)	3.39 (0.50)	3.07 (0.71)
Medium care	3.68 (0.37)	3.55 (0.37)	3.70 (0.33)	2.58 (0.48)	3.14 (0.44)	3.36 (0.43)
Emergency room	3.66 (0.54)	3.41 (0.52)	3.81 (0.59)	3.03 (0.74)	2.92 (0.61)	3.32 (0.57)
CCU - HFA	3.74 (0.63)	3.57 (0.74)	3.87 (0.58)	3.08 (0.93)	2.70 (0.64)	3.44 (0.77)
Radiotherapy	3.72 (0.56)	3.85 (0.48)	3.97 (0.37)	3.06 (0.75)	3.51 (0.39)	3.25 (0.75)
DGH	4.01 (0.52)	3.77 (0.48)	4.05 (0.46)	3.07 (0.74)	2.86 (0.56)	3.15 (0.73)
Pharmacy	3.34 (0.68)	3.59 (0.74)	3.88 (0.68)	3.16 (0.94)	2.96 (0.60)	3.36 (0.97)
Academic status						
Academic	3.65 (0.47)*	3.50 (0.50)	3.71 (0.47)*	2.91 (0.65)*	3.07 (0.49)*	3.37 (0.56)*
Non-academic	3.57 (0.63)*	3.45 (0.60)	3.61 (0.73)*	3.02 (0.76)*	2.87 (0.65)*	3.26 (0.67)*

Note. N = 1314; * Between group differences at $p < 0.05$; CCL = Cardiac Catheterization Lab; CCU - HFA = Coronary Care Unit - Heart First Aid unit; DGH = Department of Gastroenterology and Hepatology; Perc. of Management = Perceptions of Management.

Table 3

SAQ-NL Dimension Means and (Standard Deviations), Correlations, and Cronbach's α's

	Mean (*SD*)	1.	2.	3.	4.	5.	6.
1. Teamwork Climate	3.60 (0.58)	**.76**					
2. Safety Climate	3.47 (0.57)	.73	**.77**				
3. Job Satisfaction	3.65 (0.65)	.56	.54	**.84**			
4. Stress Recognition	2.99 (0.73)	-.14	-.15	-.15	**.69**		
5. Perc. of Management	3.01 (0.66)	.33	.36	.40	-.17	**.65**	
6. Working Conditions	3.13 (0.56)	.47	.48	.40	-.18	.35	**.57**

Note. N = 1314; Perc. of Management = Perceptions of Management; All correlations are significant at the $p < 0.01$ level; Cronbach's α's appear in boldface on the diagonal.

Table 4

SAQ Items, Translations, Response Rates, Means, Standard Deviations, Factor Loading, and Reliability Characteristics

Dimensions and questions	Missing (%)	Mean (*SD*)	Disagree/ agree (%)	Corrected item-total correlation	CFA factor loadings	α if item deleted (dimension)
Total scale α = .87						
Teamwork Climate						**.76**
1. Nurse input is well received in this clinical area.	3.7	3.76	7.0 / 65.8	.49	.78	.73
De inbreng van verpleegkundigen wordt op mijn unit op prijs gesteld.		(0.84)				
2. In this clinical area, it is difficult to speak up if I perceive a problem with patient care.	3.5	2.53 (0.93)	52.4 / 14.8	.40	.78	.75
Op mijn unit is het moeilijk om het uit te spreken als ik merk dat er een probleem is met de patiëntenzorg.						
3. Disagreements in this clinical area are resolved appropriately (i.e., not *who* is right, but *what* is best for the patient).	3.4	3.26 (0.87)	16.6 / 40.1	.65	1.12	.71
Meningsverschillen op mijn afdeling worden op een goede manier opgelost (d.w.z. niet wie heeft er gelijk, maar wat is het beste voor de patiënt).						
4. I have the support I need from other personnel to care for patients.	3.7	3.65	8.2 / 59.5	.57	.88	.71
Ik krijg de ondersteuning die ik nodig heb van staf-artsen om voor patiënten te kunnen zorgen.		(0.84)				
5. It is easy for personnel here to ask questions when there is something that they do not understand.	3.3	3.96 (0.76)	3.8 / 76.6	.57	.86	.72
Medewerkers op mijn unit kunnen gemakkelijk vragen stellen als er iets is dat ze niet begrijpen.						
6. The physicians and nurses here work together as a well-coordinated team.	4.1	3.48	11.9 / 48.1	.53	1.00	.72
De artsen en de rest van het team hebben hier een goede samenwerking.		(0.89)				
Safety Climate						**.77**
7. I would feel safe being treated here as a patient.	3.6	3.78	5.4 / 67.2	.56	.80	.73
Als ik hier als patiënt zou worden behandeld, zou ik me veilig voelen.		(0.79)				
8. Medical errors are handled appropriately in this clinical area.	5.0	3.38	11.3 / 43.0	.56	.90	.73
Medische fouten worden goed afgehandeld op de afdeling.		(0.84)				
9. I know the proper channels to direct questions regarding patient safety in this clinical area.	4.0	3.63 (0.94)	11.6 / 60.8	.37	.62	.76
Ik weet aan wie ik vragen kan stellen als het gaat om de patiëntveiligheid op de afdeling waar ik werk.						
10. I receive appropriate feedback about my performance.	3.6	3.29	18.0 / 42.5	.45	.74	.74
Ik krijg goede feedback op mijn functioneren.		(0.92)				
11. In this clinical area, it is difficult to discuss errors.	3.0	2.53	52.7 / 15.4	.52	.92	.73
Op de unit waar ik werk is het lastig om fouten te bespreken.		(0.93)				
12. I am encouraged by my colleagues to report any patient safety concerns I may have.	3.4	3.43 (0.86)	12.3 / 46.8	.45	.70	.74
Ik word door mijn collega's aangemoedigd al mijn bedenkingen wat patiëntveiligheid betreft te melden.						
13. The culture in this clinical area makes it easy to learn from the errors of others.	3.3	3.31 (0.86)	15.4 / 42.2	.59	1.00	.71
De cultuur op mijn unit maakt het makkelijk om van fouten van anderen te leren.						

Job Satisfaction						**.84**
14. I like my job.	5.3	4.09	3.3 / 78.3	.56	.95	.80
Ik ben enthousiast over mijn baan.		(0.78)				
15. Working here is like being part of a large family.	6.5	2.99	22.7 / 25.7	.48	1.01	.82
Het werken in dit ziekenhuis voelt als deel uit maken van een grote familie.		(0.91)				
16. This is a good place to work.	50.0	3.80	4.6 / 35.1	.57	.99	.80
Dit ziekenhuis is een goede plek om te werken.		(0.91)				
17. I am proud to work in this clinical area.	5.6	3.87	6.6 / 69.4	.63	1.20	.77
Ik ben trots dit ik in dit ziekenhuis werk.		(0.88)				
18. Morale in this clinical area is high.	4.8	3.53	14.2 / 55.3	.58	1.00	.83
Het moreel op deze afdeling is hoog.		(0.98)				
Stress Recognition						**.69**
19. When my workload becomes excessive, my performance is impaired.	4.0	3.23	26.3 / 41.7	-.15	1.16	.62
Wanneer mijn werkdruk te hoog wordt, dan lijdt mijn functioneren daaronder.		(1.05)				
20. I am less effective at work when fatigued.	6.8	2.89	34.6 / 26.1	-.06	.99	.64
Als ik vermoeid ben dan verricht ik routinetaken minder goed.		(0.96)				
21. I am more likely to make errors in tense or hostile situations.	3.8	2.99	32.2 / 30.4	-.04	1.10	.63
Ik ben meer geneigd om fouten te maken in een gespannen of bedreigende situatie.		(1.00)				
22. Fatigue impairs my performance during emergency situations.	4.9	2.82	36.6 / 24.1	-.09	1.00	.63
Vermoeidheid hindert mijn functioneren tijdens acute situaties.		(0.96)				
Perceptions of Management						**.65**
23. Management supports my daily efforts.	5.3	2.70	34.0 / 13.9	.42	2.04	.56
Het ziekenhuismanagement helpt me bij mijn dagelijkse bezigheden.		(0.87)				
24. Management doesn't knowingly compromise patient safety.	5.4	3.54	10.0 / 52.5	.39	1.59	.62
Het ziekenhuismanagement brengt de veiligheid van de patiënten niet bewust in gevaar.		(0.88)				
25. Problem personnel are dealt with constructively by our unit / hospital management.	5.8	2.63	35.8 / 9.2	.44	1.59	.61
		(0.82)				
Dit ziekenhuis gaat constructief om met minder goed functionerend personeel.						
26. I get adequate, timely info about events that might affect my work, from unit / hospital management.	4.7	2.93	29.3 / 27.5	.53	2.53	.53
		(0.94)				
Ik krijg voldoende, tijdige informatie over gebeurtenissen in het ziekenhuis die invloed kunnen hebben op mijn werk.						
27. The levels of staffing in this clinical area are sufficient to handle the number of patients.	5.2	2.89	34.5 / 31.4	.24	1.00	.67
		(1.08)				
We hebben genoeg personeel om de werklast aan te kunnen.						
Working Conditions						**.57**
28. This hospital does a good job of training new personnel.	5.3	3.20	14.5 / 32.6	.47	.93	.33
Dit ziekenhuis is goed in het trainen van nieuw personeel.		(0.82)				
29. All the necessary information for diagnostic and therapeutic decisions is routinely available to me.	5.5	3.18	18.7 / 34.3	.36	.36	.70
		(0.85)				
Ik beschik steeds over alle informatie die nodig is voor diagnostische en therapeutische beslissingen.						
30. Trainees in my discipline are adequately supervised.	4.6	3.50	13.5 / 55.1	.43	1.00	.31
Degenen die opgeleid worden in mijn discipline krijgen voldoende begeleiding.		(0.90)				

Note. *N* = 1314; Total scale and dimension Cronbach's α's appear in boldface; Dutch translated items appear in italics underneath original item. Items 2 and 11 are reverse scored.

Chapter 3

Intervention in Safety Climate: Crew Resource Management

Crew Resource Management in the ICU: The Need for Culture Change

MHTM Haerkens
DH Jenkins
JG van der Hoeven

Annals of Intensive Care 2012; 2:39

Abstract

Intensive care frequently results in unintentional harm to patients and statistics don't seem to improve. The ICU environment is especially unforgiving for mistakes due to the multidisciplinary, time-critical nature of care and vulnerability of the patients.

Human Factors account for the majority of adverse events and a sound safety climate is therefore essential. This article reviews the existing literature on aviation-derived training called Crew Resource Management (CRM) and discusses its application in critical care medicine. CRM focuses on teamwork, threat and error management and blame free discussion of human mistakes. Though evidence is still scarce, the authors consider CRM to be a promising tool for culture change in the ICU setting, if supported by leadership and well-designed follow-up.

Introduction

Despite modern equipment, continuing research and excellent training facilities our western health care system has a serious safety problem. It is estimated that out of all hospital admissions 2.9% to 16.6% suffer unintentional harm and in the United States alone up to 100,000 people may die as a result of medical errors.[1] Data from the Netherlands (2004) seem to support this with an annual number of 30.000 patients suffering preventable harm including approximately 1.735 avoidable deaths[2]. The financial cost of avoidable adverse events was estimated to be 1% of the hospital total budget.[3]

These alarming reports resulted internationally in increased pressure to improve patient safety. In line with the current safety paradigm that limiting human variability in otherwise safe systems will lead to safer care[4], this resulted in more stringent procedural guidelines. Checklists, time-outs and safety management systems were subsequently implemented.[5] Unfortunately, current efforts have not eliminated human error[2] and as expected matters are worse in the ICU environment.[6,7,8] Patients in the ICU frequently suffer from severe, multiple-system disorders that require more testing, monitoring, invasive treatment and intravenous medications than in any other hospital department.[9] Errors in this setting have a greater impact due to the increased vulnerability of the patient. The sheer number of available data essential to make a single decision is daunting. Furthermore, 'rogue' data (irrelevant but abnormal e.g. a high glucose value) unrelated to the true problem can cause a change or loss in focus on the "real" problem. This puts great pressure on multidisciplinary planning and decision making and combined with the time-critical aspects of the ICU environment increases patient risk.

Identifying the key factors in safe critical care is a challenging task. Human factors appear to play an important role.[10] Less often organizational and technical factors are involved. This is consistent with publications from other critical industries.[11]

Safety Climate

If safe critical care relies on the interdisciplinary performance of a care team as much as on individual expertise, it makes sense to establish a sound safety culture as the basis of improving patient outcomes.[12] From an anthropological standpoint, "safety culture" is only measurable by careful, long-term observations. Therefore, in the evidence-driven medical world it may be more appropriate to use the term "safety climate", which can be assessed by questionnaires. The Safety Attitudes Questionnaire (SAQ) is widely regarded to be valid, reliable, psychometrically sound and responsive to interventions.[13] Evidence from other critical industries suggests that "safety climate" correlates with unsafe and safety-specific behavior, injury rates and accidents.[14,15] Likewise, in the medical literature the "safety climate" of a hospital unit is considered one of the main contributing factors to a better quality of care.[16] How could we improve this safety climate?

The majority of current interventions focus on implementing safety tools such as event-reporting systems, quality and safety dashboards, evidence-based guidelines and checklists.[4] Even though the results of a comprehensive unit-based safety program (CUSP) are promising[13,16], introducing more stringent rules potentially increases the gap between procedure and practice.[17] Therefore, the question remains if these tools can be truly effective in the traditional hospital climate, where highly trained professionals tend to focus more on individual performance than team effectiveness.[18] Moreover, the typical culture in which junior members of the ICU staff should not question the decisions made by senior members adds to the challenge.[19]

Parallels

We can definitely learn from methods developed in other critical industries, despite the perceived procedural differences with health care.[20,21] One example is the professional civilian or military aviation industry. Until 1977, the aviation industry could be classified as a professional-centered, hierarchic working environment. This all changed with the Tenerife disaster. A KLM Boeing 747 at take-off crashed into Pan Am flight 736 still taxiing on the Los Rodeos airport runway. The accident investigation report (backed by objective cockpit voice and flight data recorder information) later revealed that human factors contributed to the deadliest mishap in aviation history, which claimed 583 lives. Ineffective radio communication with Air Traffic Control due to non-standard terminology and language barrier issues led to misinterpretation of the actual situation and a premature take-off decision of the KLM captain. The steep authority-gradient in the Dutch cockpit prevented the crew from challenging the captain's decision. As part of the solution to prevent this from happening ever again, a compulsory Human Factor training for all aircrew personnel was advised after follow-up research. This annual training, called Crew Resource Management (CRM), was developed in 1979 in a workshop sponsored by NASA.[22] CRM has meant a huge leap forward in improving aircrew team performance in civilian as well as in military aviation. The focus of CRM is on threat and error management and early identification with blame free countering of human mistakes. CRM training is now mandatory for professional aircrew in Europe and the United States.

How does this fit in the intensive care environment? In the ICU there is inherently much emphasis on technical skills and not on communication, teamwork and leadership. These latter skills are rarely deliberately taught or sought after from applicants[21], resulting in critical care practitioners being relatively unprepared to meet the demands of the increasingly complex ICU environment.[1,23] This is the basis for suboptimal coordination of multidisciplinary care and the resultant high number of ICU errors.[24] The

traditional critical care environment has a tendency to focus on the performance of a particular practitioner rather than on the system of care.

In aviation, nontechnical skills, a blame-free environment and Team Situational Awareness (SA) are considered CRM core competencies that require specific and focused training.[25] Team SA is defined as the ability to identify, process, and comprehend the critical elements of information about what is happening to the team with regards to the mission. Team SA is considered to be the basis for effective decision making in critical environments and a core competence for any professional team. The archetypical medical specialist's personality (highly motivated, A-type, control freak) helps to create an environment in which a junior team member could feel inhibited to offer input in a senior team with "vertical" leadership. This impacts Team SA, posing a threat to process safety, and thus patient safety.[23]

Where is the evidence?

ICUs with a "team-oriented culture" have shorter lengths of stay, lower nursing turnover, higher quality of care and can better meet family members' needs.[26] As discussed earlier, general information on a department's safety climate may be obtained by questionnaires and reviews of complication data.[16] Objective team performance data in regards to specific adverse events is hard to obtain. Although the patient monitor and ventilator store data, the process by which decisions are made is only available afterwards in the form of doctor's and nurse's notes. Video monitoring with voice recording is not widely available for debriefing purposes. This limits the visibility of the role of Human Factors in peer reviews and morbidity and mortality conferences. The effect of national rules and regulations cannot be overestimated. In the United States, according to the Health Insurance Portability and Accountability Act (HIPAA), the simple concept of video recording a trauma resuscitation requires review by a lawyer and, according to the Joint Commission in the

United States, patient permission and is, thus, not a widely accepted practice. To date, no evidence is available from the ICU environment that CRM training improves patient safety. Notably, most team training evaluations have been conducted in the military and aviation environment.[27] These results look promising, and recent evidence also shows a positive effect of team training in the operating room.[28,29] Neily et al. analyzed surgical mortality data from 108 Veterans Affairs Hospitals and showed that a Medical Team Training program resulted in significant reduction in surgical mortality rates.[29] Unfortunately, results from other authors are less favourable. Even though non-technical skills, attitudes and teamwork climate seem to improve, no significant effect on operating time or length of hospital stay (LOS) was found.[30] Considerable cultural resistance to adoption is encountered, particularly among medical staff. Debriefing and challenging authority seemed more difficult to adopt than other parts of the training.[30]

Changing the climate: implementation

Crew Resource Management training for Royal Netherlands Air Force (RNLAF) aircrew is a 2-day full-time interdisciplinary training. The training syllabus consists of lectures in cognitive psychology and multiple interactive sessions using realistic data.

Key subjects in the CRM-syllabus are:

- Situational Awareness and recognition of adverse situations
- Human errors and nonpunitive response
- Communication and crosscheck techniques
- Give and receive performance feedback
- Management of stress, workload and fatigue
- Creating and maintaining team structure and climate
- Leadership
- Risk management and decision-making

Any CRM-training has to meet Federal Aviation Authority (FAA) or Joint Aviation Authority (JAR) regulations. Not only do they define the various subjects but also the extent to which each subject should be discussed and set limits for refresher training. This standardization is a major contributing factor to the success of CRM.

Medical CRM-training has no international standard yet. Medical Human Factors awareness training initiatives may vary in curriculum, duration, intensity and follow-up support. The U.S. Department of Defense's Patient Safety Program developed TeamSTEPPS, an evidence-based teamwork system, in collaboration with the Agency for Healthcare Research and Quality (AHRQ). TeamSTEPPS has been implemented in a variety of clinical settings and shown team performance improvement in pediatric and surgical ICUs.[32] Still, any hospital department deciding that CRM is the way forward to improve patient safety should realize that it is not just a single shot training investment (which can be very effective in itself)[29] but part of a culture intervention. There will be understandable reluctance in the medical community to accept the necessity of a CRM-culture intervention in their professional environment. Even though further studies are needed to define the optimal training package[29], some basic guidelines may be given.

1. CRM training. The goal of this training is creating awareness of the human factors that influence team performance. We suggest a 2-day full time training containing the key subjects of aviation CRM as discussed above. Because the multidisciplinary ICU environment requires a different non-technical skillset than a cockpit, medical CRM training should be tailored to the specific department's environment. This is where some current training initiatives fall short. Tailoring CRM-training to the specific needs of an ICU requires insight in the specific clinical processes and culture.[31] ICU professionals have no tradition in briefing and debriefing techniques and performance feedback.

ICU-CRM training should therefore emphasize:

- Briefing and debriefing skills using exercises and actual ICU video footage
- Effective use of checklists
- Identifying team roles
- Promoting structure, reduction of ineffective communication
- Performance feedback as an essential requirement in CRM. This starts with careful consideration of timing and relevance of the message, followed by three levels of performance feedback. The first level requires the team member to formulate the message short, clear and non-blaming ("Doctor, I'm not sure we did all the checks…"). The second level contains a key word that has a defined value ("Doctor, I'm not comfortable with that decision…"). If this feedback is ignored, and the situation is considered unacceptable the last resort could be a request to "stop the procedure".

One CRM-tool used at the Mayo Clinic to help facilitate accurate communication in stressful medical situations is based on the work by Patterson et al.[33] Medical personnel are taught how to communicate without creating conflict or in the face of apparent conflict. This model has proven useful while multiple other endeavors have been created and implemented to foster the ultimate safe environment.
We are currently developing evidence-based requirements for a national ICU-CRM training curriculum in the Netherlands. The basis is a 2-day CRM-training using lectures, video-feedback and interactive exercises. This training is followed by a 1-year implementation phase in which a core group of department professionals is coached by a CRM trainer. Results will be published in the near future.

2. CRM implementation. To be successful, the culture change should be supported by additional measures. A core group of ICU-professionals should receive extra coaching during the year after the training to be able to integrate and develop the new way of professional interaction within the ICU-department. Even though CRM relies on intrinsic motivation to be

effective, the department leadership needs to clarify to all staff beforehand that CRM is not a noncommittal system but will serve as a yardstick for professional evaluation too. This requires leadership by example.

3. CRM and simulation. The effect of CRM-based culture change is reinforced by the use of scenario-based team training exercises, again derived from aviation simulation expertise.[34] Simulation creates a zero-risk environment that allows medical teams to practice high-risk, low frequency events without endangering patients.[25] This training can either be done in an artificial "laboratory" environment or "in situ"-training, which is conducted on actual patient care units involving actual health care team members and actual organization processes.[33] Simulation - if well debriefed - has many advan-tages, but if used as a stand-alone modus without the basis of CRM-training holds the risk of focusing too much on technical skills and single-task performance.[35] This will result in a limited impact on patient safety. The key to the success of team training tools in health care is the identification of the domain-specific team skills required for effectively managing routine and emergency scenarios effectively.[36] We suggest implementing two separate phases of simulation training: the first level of training mainly focuses on technical skills and then CRM-training (classroom) followed by second level simulation training that focuses on non-technical performance.

4. CRM retention. Research in military aviation shows that retention of the CRM-subject matter and the effect on aircrew attitude degrades after 3 years. Therefore CRM refresher training in the RNLAF is scheduled every 3 years.[37] Whether the hospital setting calls for a similar refresher-schedule or regular well-debriefed simulation sessions are effective enough is still unclear. Chapter 6.1 of this thesis explores this issue.

Conclusions

Human Factors account for the majority of adverse events in aviation as well as in clinical medicine. The current safety paradigm is still based on ways to limit human variability in otherwise safe systems, promoting

stringent procedural guidelines. CRM focuses on improving interprofessional cooperation and team performance and thus patient safety. Even though evidence of CRM on medical errors and patient outcome is still scarce, the parallels between the critical processes in aviation and Intensive Care suggest that a well-adapted medical CRM training has potential for the ICU environment too.

List of abbreviations

AHRQ: Agency for Healthcare Research and Quality (United States)
CRM: Crew Resource Management
CUSP: Comprehensive Unit-based Safety Program
FAA: Federal Aviation Authority (United States)
HIPAA: Health Insurance Portability and Accountability Act (United States)
ICU: Intensive Care Unit
JAR: Joint Aviation Authority (Europe)
LOS: Length of Hospital Stay
NASA: North American Space Administration
RNLAF: Royal Netherlands Air Force
SA: Situational Awareness
SAQ: Safety Attitudes Questionnaire

References

1. Kohn LT, Corrigan JM, Donaldson MS: *To err is human: building a safer health system*. Washington: National Academy Press; 2000.
2. Wagner C, Zegers M, De Bruijne MC: *Patient safety: unintended and potentially preventable adverse events within surgical specializations.* Ned Tijdschr Geneeskd 2009; 153:327-333.
3. Kievits F, van Maanen H: *Kosten ziekenhuisfouten becijferd [Hospital costs accounted for]*. Ned Tijdschr Geneeskd 2009; 153:476.
4. Dekker S: *Doctors are more dangerous than gun owners: a rejoinder to error counting.* Lund University School of Aviation Tech report 2006-01; 2006.
5. de Vries EN, Prins HA, Crolla RMPH, et al: *Effect of a Comprehensive Surgical Safety System on Patient Outcomes.* N Engl J Med 2010; 363:1928-1937.
6. Donchin Y, Gopher D, Olin M, et al: *A look into the nature and causes of human errors in the intensive care unit*. Crit Care Med 1995; 23:294-300.
7. Cook TM: *Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 2: intensive care and emergency departments.* Br J Anaesth 2011; 106:632-642.
8. Foster AJ, Worthington JR, Hawken S, et al: *Using prospective clinical surveillance to identify adverse events in hospital.* BMJ Qual Saf 2011; 20:756-763.
9. Boyle D, O'Connell D, Platt FW, Albert RK: *Disclosing errors and adverse events in the intensive care unit*. Crit Care Med 2006; 5:1532-1537.
10. Bion JF, Abrusci T, Hibbert P: *Human factors in the management of the critically ill patient*. Br J Anaesth 2010; 105:26-33.
11. Reason J: *Understanding adverse events: human factors.* Qual Health Care 1995; 4:80-89.
12. Paine LA, Rosenstein BJ, Sexton JB, et al: *Assessing and improving safety culture throughout an academic medical centre: A prospective cohort study.* Postgrad Med J 2011; 87:428-435.
13. Colla JB, Bracken AC, Kinney LM, et al: *Measuring patient safety climate: a review of surveys.* Qual Saf Health Care 2005; 14:364-366.
14. Cooper MD, Phillips RA: *Exploratory analysis of the safety climate and safety behavior relationship.* Journal of Safety Research 2004; 35: 497-512.

15. Nielsen KJ, Mikkelsen KL: *Predictive factors for self-reported occupational injuries at 3 manufacturing plants.* Safety Science Monitor 2007; 2:1-9.
16. Sexton JB; Berenholtz SM; Goeschel CA, et al: *Assessing and improving safety climate in a large cohort of intensive care units.* Crit Care Med 2011; 5:934-939.
17. Dekker S: *The re-invention of human error. Lund university School of Aviation Tech report* 2002-01; 2002.
18. Dismukes RK, Berman B: *Checklists and monitoring in the cockpit: why crucial defenses sometimes fail.* NASA-Ames Research Center Moffet Field, California: Technical Memorandum NASA/TM-2010-216396; 2010.
19. Schaeffer H, Helmreich R: *The operating room management attitudes questionnaire (ORMAQ).* Austin, Texas: NASA/University of Texas Technical Report 93-8; 1993.
20. Legemate DA: *Safety first.* Ned Tijdschr Geneeskd 2009; 153:313.
21. Brindley PG: *Patient safety and acute care medicine: lessons from the future, insights from the past.* Crit Care 2010; 14:217.
22. Cooper GE, White MD, Lauber JK: *Resource management on the flightdeck: proceedings of a NASA/industry* workshop NASA-Ames Research Center Moffett Field, CA: NASA CP-2120; 1980.
23. Strack van Schijndel RJM; Burchardi H. Bench-to-bedside review: *Leadership and conflict management in the intensive care unit.* Crit Care 2007; 11:234.
24. Garrouste-Orgeas M: *Selected Medical Errors in the Intensive Care Unit.* Am J Respir Crit Care Med 2010; 181:134-142
25. Eisen LA, Savel RH: *What went right: Lessons for the intensivist from the crew of US Airways Flight 1549.* Chest 2009; 136:910-917.
26. Stockwell DC, Slonim AD: *Quality and Safety in the Intensive Care Unit.* J Intensive Care Med 2006; 21:199-210.
27. Salas E, DiazGranados D, Klein C: *Does team training improve team performance?* Human Factors 2008; 6:903-933.
28. Ricci MA, Brumsted JR: *Crew Resource Management: Using Aviation Techniques to Improve Operating Room Safety.* Aviation, Space, and Environmental Medicine 2012; 4: 441-444
29. Neily J, Mills PD, Young-Xu Y, et al: *Association Between Implementation of a Medical Team Training Program and Surgical Mortality.* JAMA 2010; 15:1721-1722.

30. McCulloch P, Mishra A, Handa A, et al: *The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre.* Qual Saf Health Care 2009; 18:109-115.
31. Hamman WR; Beaudin-Seiler BM; Beaubien JM: *Understanding interdisciplinary health care teams: using simulation design processes from the air carrier advanced qualification program to identify and train critical teamwork skills.* J Patient Saf 2010; 6:137-146.
32. Mayer CM; Cluff L; Lin WT, et al: *Evaluating Efforts to Optimize TeamSTEPPS Implementation in Surgical and Pediatric Intensive Care Units.* Jt Comm J Qual Patient Saf 2011; 37:365-374.
33. Patterson K, Grenny J, McMillan R, et al: *Crucial Conversations: tools for talking when stakes are high.* McGraw Hill New York, 2002.
34. Lighthall GK, Barr J, Howard SK, et al: *Use of fully simulated intensive care unit environment for critical event management training for internal medicine residents.* Crit Care Med 2003; 10:2437-2443.
35. Thomas EJ: *Improving teamwork in healthcare: current approaches and the path forward.* BMJ Qual Saf 2011; 20:647-650.
36. Reader TW, Cuthbertson BH: *Teamwork and team training in the ICU: Where do similarities with aviation end?* Critical Care 2011; 15:313
37. Koppes R: *The effect of RNLAF CRM training on participant attitude and retention over time.* MSc Thesis. Cranfield University; 2009.

Chapter 4

Impact of CRM in the Intensive Care Unit

Crew Resource Management in the Intensive Care Unit: a prospective three-year cohort study

MHTM Haerkens
M Kox
J Lemson
S Houterman
JG van der Hoeven
P Pickkers

Acta Anaesthesiologica Scandinavica 2015; 59:10, 1319–1329

Abstract

Background

Human factors account for the majority of adverse events in both aviation and medicine. Human factors awareness training entitled "Crew Resource Management" (CRM) is associated with improved aviation safety. We determined whether implementation of CRM impacts outcome in critically ill patients.

Methods

We performed a prospective three-year cohort study in a 32-bed ICU, admitting 2500-3000 patients yearly. At the end of the baseline year all personnel received CRM training, followed by 1 year of implementation. The third year was defined as the clinical effect year. All 7271 patients admitted to the ICU in the study period were included.

The primary outcome measure was ICU complication rate. Secondary outcome measures were ICU- and hospital length of stay, and standardized mortality ratio.

Results

Occurrence of serious complications was 67.1/1000 patients and 66.4/1000 patients during the baseline and implementation year respectively, decreasing to 50.9/1000 patients in the post-implementation year (p=0.03). Adjusted odds ratios for occurrence of complications were 0.92 (95%CI 0.71-1.19, p=0.52) and 0.66 (95%CI 0.51-0.87, p=0.003) in the implementation and post-implementation year. The incidence of cardiac arrests was 9.2/1000 patients and 8.3/1000 patients during the baseline and implementation year, decreasing to 3.5/1000 patients (p=0.04) in the post-implementation year, while cardiopulmonary resuscitation success rate increased from 19% to 55% and 67% (p=0.02). Standardized mortality-ratio decreased from 0.72 (95%CI 0.63-0.81) in the baseline year to 0.60 (95%CI 0.53-0.67) in the post-implementation year (p=0.04).

Conclusion

Crew Resource Management-implementation is associated with a reduction in serious complications and lower mortality in critically ill patients.

Introduction

To err is human. As a result everything that a human being devises, uses, or does is prone to error and failure. Human factors refer to environmental, organizational and job factors, and to human and individual characteristics which influence professional behavior in a way that affects performance and safety.[1] Human factors account for the majority of adverse events in aviation. Human factors awareness training entitled 'Crew Resource Management' (CRM) was introduced in 1979 for aircrew after a series of accidents in which human factors were found to be the root cause.[2] Following the implementation of CRM, a decrease in events led to CRM becoming the present day aviation operational standard.[3,4] Especially during time critical cockpit emergencies CRM is considered vital for aircrew effectiveness, although sound scientific proof of CRM effectiveness in aviation is lacking.

In clinical medicine, human factor related errors can have a major impact on patient safety.[5,6] This is especially so in departments where high risk, time critical procedures on vulnerable patients are performed in a multidisciplinary team setting, human factors are likely to play an important role.[7] Indeed, in critically ill patients the occurrence of complications is related to outcome.[8]

The defining aspect of CRM is a system approach to safety culture. Rather than focusing on individual failure, CRM aims to identify system flaws and uses standardized communication tools to improve process effectiveness and safety[9]. The message of "good people are set up to fail in bad systems let's figure out how to keep everyone safe" is more easily accepted than "you have a problem that needs to be corrected".[10] This approach is fundamentally different from conventional quality and safety programs in medicine that focus on limiting variation in human behavior through regulations, or scenario-based team training.[11,12] Contrary to aviation, there is currently no international standard for medical CRM training.

While the parallels between the critical processes in aviation and medicine suggest that a well-adapted medical CRM training may have potential to improve patient safety, evidence of the effects of CRM on patient outcome in a clinical setting is limited. Closed format Intensive Care Units (ICUs) facilitate both CRM implementation and effect evaluation. The aim of this study was to assess the effects of CRM implementation on outcome in critically ill patients.

Materials and Methods

Department and training organization

Radboud University Medical Center (Radboudumc) is a 953 bed, tertiary-care academic hospital with approximately 32,000 admissions annually. The 32-bed ICU admits 2500-3000 patients yearly, of which approximately 1000 are cardio-thoracic surgery patients. Radboudumc's ICU workforce (in FTE) includes 16 consultants, 9 fellows, 22 residents, and a nursing staff of 173. The independent aerospace training organization that provided the CRM training consisted of five trainer/coaches (senior military and commercial airline pilots, psychologists and medical specialists of which some are dual-qualified). All were proficient in the area of operational human factors as well as CRM development and training.

CRM intervention

With the decision to implement CRM in the ICU, it was decided to evaluate its effects prospectively. Because of the nature of the intervention (team training), it was not feasible to perform a study using a control arm. For this reason the pre-during-post design was chosen. Therefore, a 'baseline year', 'implementation year', and 'post-implementation year' were designated. In the two years preceding the study we had a stable baseline complication rate, but as we could not perform data quality checks retrospectively, we decided not to use these data, and only use the prospective data obtained during the baseline year prior to implementation of CRM. At the end of the baseline year, all ICU personnel (attending physicians, nurses and residents)

received a two-day (8 contact hours per day) CRM awareness training in multidisciplinary groups of a maximum of 15 participants within a three-month window. All training sessions were conducted by two trainers and were held at a training facility at some distance to the Radboudumc campus to minimize interference. The course included lectures on human factors and principles of CRM, and multiple interactive sessions using realistic data such as case studies and video footage from the Radboudumc ICU department. The training emphasized eight key areas: situational awareness[13,14] and recognition of adverse situations, human errors and non-punitive response, communication and briefing and debriefing techniques, providing and receiving performance feedback, management of stress, workload and fatigue, creating and maintaining team structure and climate, leadership in a flat hierarchy environment, and risk management and decision-making (see[15] or Supplemental File for more detailed information on training curriculum). Each training group created a shortlist of practical "action points" to be used in the following implementation year, during which the CRM principles were forged into custom-made and practical clinical tools such as standardized briefings and debriefings, checklists and noise (static) reduction methods. We considered the after-training follow-up to be crucial for the success of a CRM-intervention.

The follow-up during the implementation year consisted of several measures: a "CRM Core Group" was formed, CRM became a standard item in staff meetings, non-facultative scenario based team training sessions were planned and CRM-training was provided to all new personnel. Moreover, regular process observation took place.

The CRM Core Group consisted of three intensivists, 11 ICU nurses, and the ICU's patient safety officer. Under additional coaching from a CRM-instructor the Core Group coordinated translation of the CRM action points into clinical practice, and created professional ownership. This group interfaced regularly with the department's medical and nursing staff and organized several activities such as a plenary kick-off meeting, an annual dedicated "week of CRM", refresher lectures, and awarded the "CRM-performer of the year". The CRM Core Group posted regular information bulletins on the ICU intranet

page and developed several checklists for common ICU procedures, including central venous line placement, endotracheal intubation, tracheotomy and handover during patient admission and transfer. In addition, CRM became a standard agenda item during the two-weekly staff meetings and yearly individual evaluations.
Furthermore, to secure the CRM lessons learned in daily practice, scenario-based team training was conducted during the implementation year. This team training was conducted in an in-hospital training location, using simulation manikins and CRM-trained clinical supervisors. As with the CRM-training, the scenario based team training was non-facultative, used a multidisciplinary setting and involved the whole staff.
All new personnel (13 nurses and 2 Intensive Care fellows) also received the regular two-day CRM training.
Finally, three times a year during a two-week period designated senior ICU nurses were given the responsibility to observe an ICU-unit whenever any invasive procedure took place. The resulting information was reported to the ICU's safety officer, who presented the collected info to the CRM core team. No data were provided to the staff during the data collection period.

Data collection
Patient clinical outcome data was collected from the Dutch National Intensive Care Evaluation (NICE) database.[16] The NICE classification system is not based on Clavien-Dindo or the AMA-master classification system. The Dutch ICU complication registration was developed by a subcommittee of the Dutch Society for Intensive Care Medicine and started with a questionnaire in which individual members were able to make suggestions for potential complications that should be included in the final registry. Out of 68 potential complications a final list was constructed by the subcommittee based on the following prerequisites: 1) existing evidence in the literature that the complication relates to patient damage, 2) complication must be either severe or frequent, 3) the complication must be clearly defined and measurable, 4) the complication must be preventable by taking appropriate measures. The final list was approved by all Dutch Society for Intensive

Care Medicine members and included in the NICE registration.[16,17] All complications were registered daily by a consultant intensivist. To prevent incorrect (e.g. double) registration the data were subsequently checked by the departmental database manager and rechecked by the national NICE organization. Furthermore the NICE organization performs on-site data audits to monitor the quality of the data. Data was encrypted by the removal of all patient-identifying information. In the Netherlands, there is no need to obtain consent to use such registries with anonymous data. The NICE initiative is officially registered in accordance with the Dutch Personal Data Protection Act. The study was carried out in accordance with the applicable rules concerning the review of research ethics committees and informed consent. Data collection was standardized according to strict definitions and was subject to stringent quality checks.

To determine the effect of CRM implementation on complication incidence, we used a predetermined set of 18 complications obtained from the NICE database.[16,17] Data was collected during the baseline year preceding the three-month CRM training phase (August 2009 to end of July 2010), the implementation year following the training phase (November 2010 to end of October 2011), and the post-implementation year (November 2011 to end of October 2012).

The primary outcome measure was overall ICU complication rate, of which the incidence of cardiac arrest and cardiopulmonary resuscitation (CPR) success rate had our special interest. Cardiac arrest incidence is considered a measure of quality of care[18] and, as few clinical interventions rely on team-work to such an extent as CPR, outcome was deemed a relevant endpoint as well. Secondary outcome measures were ICU- and hospital length of stay, and standardized mortality ratio. Furthermore, as evidence from other critical industries[19] and clinical settings[20-23] suggests a positive relationship between safety climate and safety outcome we measured the ICU's safety climate prior to and following the implementation year. Safety climate was determined by the Safety Attitudes Questionnaire (SAQ) using a Likert scale transformed to a 100-point scale.[24] The SAQ is a validated healthcare derivative of the Cockpit Management Attitudes Questionnaire.[20,25]

All CRM participants were invited to fill out a validated Dutch translation of the SAQ "(described in Chapter two of this thesis)" during the baseline year and at the end of the implementation year. During the implementation period process surveillance was conducted to monitor professional compliance: experienced observers scored 3-4 times per year during several weeks how many critical process opportunities suitable for CRM tools occurred and in what portion they were actually used.

Statistical analysis

Mann-Whitney U-tests were used to compare continuous data between two groups, Kruskall Wallis tests were used to compare continuous data between three or more groups, and chi-square tests were used to compare proportions. We used an uncorrected chi-square test to evaluate our null hypothesis. In addition, multivariate logistic regression analysis was performed using APACHE IV probability score as a covariate to correct for differences in disease severity. To correct for possible differences in baseline patient characteristics, standardized mortality ratios (SMRs), their 95% CI, and differences between SMRs were calculated as described previously.[26,27] A two-tailed p-value of less than 0.05 was considered statistically significant. Differences were not corrected for multiple testing because of the explorative nature of the study. With an estimated baseline complication rate of approximately 60-80/1000 patients, a power of 80%, and a two-sided alpha of 0.05, 2500 patients per cohort were required to detect an absolute change in complications of 20/1000 patients. Data was analyzed using SPSS Statistics 20 (IBM Corp., Armonk, NY, USA) and MedCalc 11.3.1.0 (MedCalc software, Oostend, Belgium).

Results

Patient data

The three cohorts consisted of 2295 (baseline year), 2423 (implementation year), and 2553 (post-implementation year) patients. During the three-year study period no relevant changes in staffing levels, device use, or protocols/

procedures occurred, except for the ICU moving to another location in the hospital in December 2011. Patient characteristics are listed in Table 1. A significant decrease in complication incidence rate was observed: from 67.1/1000 patients in the baseline year and 66.4/1000 patients in the implementation year to 50.9/1000 patients in the post-implementation year (Figure 1, Table 2). Using the APACHE IV probability score as a covariate, the adjusted odd ratios for the occurrence of one or more complications were 0.92 (95% CI 0.71-1.19, p=0.52) and 0.66 (95% CI 0.51-0.87, p=0.003) in the implementation and post-implementation year, respectively.

Changes in the incidence per complication diagnosis are depicted in Table 2. The incidence of critical illness polyneuropathy/myopathy and cardiac arrests on the ICU decreased significantly. Using the APACHE IV probability score as a covariate, the adjusted odd ratios for critical illness polyneuropathy/myopathy were 0.52 [CI 0.25-1.06, p=0.07] and 0.26 [CI 0.11-0.63, p=0.002] in the implementation and post-implementation year, respectively. Adjusted odds ratios for cardiac arrests on the ICU were 0.87 [CI 0.47-1.62, p=0.66] and 0.33 [CI 0.15-0.73, p=0.006] in the implementation and post-implementation year, respectively. Apart from the decrease in incidence of cardiac arrests, the CPR success rate increased from 19% in the baseline year to 55% and 67% in the implementation and post-implementation year (Figure 2).

As expected, the occurrence of complications was associated with mortality (APACHE IV adjusted odds ratio of 1.97 [95% CI 1.44-2.70, p<0.0001]). Finally, the standardized mortality ratio was 0.72 (95% CI 0.63-0.81) in the baseline year, 0.69 (95% CI 0.61-0.78) in the implementation year, and 0.60 (95% CI 0.53-0.67) in the post-implementation year (baseline vs. post-implementation year: p=0.04).

No clinically relevant effects on ICU- or hospital-length of stay were observed.

Safety climate assessment

Following CRM implementation, perceived safety climate significantly improved in 5 out of 6 Safety Attitudes Questionnaire-domains: teamwork

climate, safety climate, perceptions of management, working conditions, and job satisfaction (Table 3). Changes within disciplines (medical staff, nurses, other) are listed in Table 4 (Supplemental Digital Content).

Process surveillance

The surveillance from June and September 2012 showed that during 21 observational days checklist use and briefing were performed in 70-90%. Debriefing performed between 55 and 71%. Structured handovers scored between 55 and 70%.

Discussion

This study indicates an association between CRM implementation in the ICU and a lower incidence of predefined complications in critically ill patients. Of special interest, cardiac arrests on the ICU occurred less frequently following implementation of CRM, and a higher CPR success rate was observed.

In addition, we found that the occurrence of complications was associated with mortality and that implementation of CRM was associated with a reduced standardized mortality rate. These clinically relevant effects paralleled a positive impact on the perceived safety climate by the health care providers.

Several factors may explain the positive effects of CRM implementation on clinical end points in the present study. In the first place, we introduced CRM from the perspective of correcting system flaws rather than individual shortcomings, an approach which has been shown to be effective in convincing professionals10. In addition, firm commitment and visible support from the department's leadership was present.[10,15] Secondly, every CRM-training was conducted by two trainers combining extensive operational experience in clinical medicine, military and commercial aviation, and cognitive psychology. As, in contrast to aviation, medical CRM has no accepted standard yet, their credible operational background was

instrumental in convincing ICU professionals of the potential gains of CRM and implementing a new professional and team identity in a department. Thirdly, a core group of ICU-professionals was formed to develop and integrate the new way of professional interaction within the ICU. As this group played a pivotal role in creating professional ownership, they received additional coaching from a CRM-instructor during the implementation year and likely optimized training impact. Fourthly, to prevent dilution of human factors awareness the CRM intervention project included not only the initial training period, but also the subsequent training of new staff. Fifthly, some checklists were (re)designed. As checklists appear to be independent effective tools for improving patient safety[28,29], it is difficult to separate their impact on results from the CRM-effort. In spite of the fact that we cannot exclude a positive influence of a (re)designed checklist on our results we are convinced that the implementation of a checklist document has less effect on patient safety than the way the team works with the document (e.g. briefing and crosscheck techniques), especially because checklists were already in use at the department before the intervention. As we consider checklists a separate - if valuable - safety tool, the CRM-training focused on checklist use, not design.
Finally, to secure the CRM lessons learned in daily practice, scenario-based team training was conducted during the implementation year.[15,30]

Several limitations of the present study need to be addressed. Most importantly, this study was a non-randomized single-centre study. The intensity and duration of the implementation process importantly limited the feasibility of other study designs. In spite of this limitation we believe that the decrease in complication rate and SMR can be related to the CRM-intervention. In the two years preceding the study baseline complication rate was stable, but as these registrations could not be validated retrospectively, this data was not used. Furthermore, during the whole study period there were no changes in interventions that are known to reduce morbidity or mortality in the ICU such as strict glucose regulation, early goal-directed therapy, use of corticosteroids, prone positioning and low tidal volume

ventilation. The fact that the ICU moved to another location in the hospital appears unlikely a confounder of our results, as no relevant changes in procedures, staffing levels, technical infrastructure or other major changes that could influence patient management occurred. Nevertheless, some differences in patient characteristics between the different study periods were observed. It could be argued that the risk of a complication is related to the severity of illness. Importantly, after correction for severity of illness, implementation of CRM was still associated with a reduction in relevant complications and mortality. The additional association between the occurrence of a complication and mortality supports the notion that CRM accounts for the bene-ficial effects on mortality observed.

Additionally, the occurrence of critical illness polyneuropathy/myopathy is related to disease severity. As such, our finding of reduced incidence of critical illness polyneuropathy/myopathy is consistent with the notion that CRM is associated with improved care and reduced disease severity. Nevertheless, we emphasize that a direct link between the reduced incidence and the CRM implementation is not possible.

In addition, a direct link between a specific action and patient outcome, e.g., using data logging equipment (comparable to aviation's cockpit voice recording and flight data recording) was not determined. Even though video logging of ICU procedures would be technically possible, there still is considerable reluctance in the medical professional community due to legal and patient privacy issues.[29]

Finally, because the Safety Attitude Questionnnaire's response rate after training was relatively low (51%). Low response rates may increase the risk of a non-response bias.

Perceived safety climate is positively related to safety outcomes both in hospital settings and other high-hazard fields.[21,32,33] Previous studies on the impact of safety climate on safety outcome have focused on either the effect of team training on perceived safety climate[34,35], or assessed patient outcome.[36] Implementation of CRM resulted in a culture change and a safer environment, illustrated by a decrease in malpractice expenses.[37]

To our knowledge, our concordant observation that complication rates and mortality decreased represents the first clear association between CRM training, clinical outcome, and perceived safety climate. To date, no prospective randomized trials evaluating the implementation of CRM are available.
A large nationwide retrospective study, with a contemporaneous control group, in surgical patients reported a decrease in the overall mortality rate in (non-randomized) hospitals that participated in a training program focused on briefings and debriefings in the operating room (including the use of checklists), while no decrease in mortality rate was observed in the control group. In this study risk-adjusted mortality rates did not reach a statistically significant difference between the trained and non-trained institutes.[38]

In conclusion, our data indicate an association between CRM implementation and a reduction of complication rate and mortality in critically ill patients as well as an improved perceived safety climate. To our knowledge, this is the first study that links CRM to improved clinical outcome. In view of these results and absence of deleterious side effects for the patients, one might argue that, similar to aviation, widespread implementation of CRM in the ICU is justified, even without higher levels of evidence obtained from randomized clinical trials.

Acknowledgements

The authors would like to thank Sjef van der Velde for data extraction from the hospital NICE database.

References

1. Dempsey PG, Wogalter MS, Hancock PA. *Defining ergonomics/human factors.* W Karwowski (Ed) International Encyclopedia of Ergonomics and Human Factors (Second Edition), London: Taylor and Francis 2006; 32-35.
2. Cooper GE, White MD, Lauber JK. *Resource management on the flightdeck: proceedings of a NASA/industry workshop.* NASA-Ames Research Center Moffett Field: NASA CP-2120, 1980.
3. Commission Regulation (EU) No 965/2012, chapters ORO.FC.115: *Crew resource management (CRM) training, and ORO.FC.215:* Initial operator's crew resource management (CRM) training.
4. FAA Part 121: *Operating Requirements: Domestic, Flag, and Supplemental Operations,* article §121.404 Compliance dates: Crew and dispatcher resource management training.
5. Brindley PG. *Patient safety and acute care medicine: lessons for the future, insights from the past.* Crit Care 2010; 14: 217.
6. In: Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err is Human: Building a Safer Health System.* Washington (DC), 2000.
7. Garrouste-Orgeas M, Timsit JF, Vesin A, Schwebel C, Arnodo P, Lefrant JY, Souweine B, Tabah A, Charpentier J, Gontier O, Fieux F, Mourvillier B, Troche G, Reignier J, Dumay MF, Azoulay E, Reignier B, Carlet J, Soufir L. *Selected medical errors in the intensive care unit: results of the IATROREF study: parts I and II.* Am J Respir Crit Care Med 2010; 181: 134-42.
8. Giraud T, Dhainaut JF, Vaxelaire JF, Joseph T, Journois D, Bleichner G, Sollet JP, Chevret S, Monsallier JF. Iatrogenic complications in adult intensive care units: a prospective two-center study. Crit Care Med 1993; 21: 40-51.
9. Flin R, Maran N. *Identifying and training non-technical skills for teams in acute medicine.* Quality & safety in health care 2004; 13 Suppl 1: i80-4.
10. Leonard M, Graham S, Bonacum D. *The human factor: the critical importance of effective teamwork and communication in providing safe care.* Quality & safety in health care 2004; 13 Suppl 1: i85-90.
11. Gjeraa K, Moller TP, Ostergaard D. *Efficacy of simulation-based trauma team training of non-technical skills. A systematic review.* Acta Anaesthesiol Scand 2014; 58: 775-87.

12. Siassakos D, Hasafa Z, Sibanda T, Fox R, Donald F, Winter C, Draycott T. *Retrospective cohort study of diagnosis-delivery interval with umbilical cord prolapse: the effect of team training.* BJOG : an international journal of obstetrics and gynaecology 2009; 116: 1089-96.
13. Schulz CM, Endsley MR, Kochs EF, Gelb AW, Wagner KJ. *Situation awareness in anesthesia: concept and research.* Anesthesiology 2013; 118: 729-42.
14. Dekker SW. *Crew situational awareness in high-tech settings: tactics for research into an ill-defined phenomenon.* Transportation Human Factors 2000; 2: 49-62.
15. Haerkens MH, Jenkins DH, van der Hoeven JG. *Crew resource management in the ICU: the need for culture change.* Ann Intensive Care 2012; 2: 39.
16. Arts D, de Keizer N, Scheffer GJ, de Jonge E. *Quality of data collected for severity of illness scores in the Dutch National Intensive Care Evaluation (NICE) registry.* Intensive Care Med 2002; 28: 656-9.
17. de Vos M, Graafmans W, Keesman E, Westert G, van der Voort PH. *Quality measurement at intensive care units: which indicators should we use?* J Crit Care 2007; 22: 267-74.
18. Hillman K, Chen J, Cretikos M, Bellomo R, Brown D, Doig G, Finfer S, Flabouris A, investigators Ms. *Introduction of the medical emergency team (MET) system: a cluster-randomised controlled trial.* Lancet 2005; 365: 2091-7.
19. Cooper MD, Phillips RA. *Exploratory analysis of the safety climate and safety behavior relationship.* J Safety Res 2004; 35: 497-512.
20. Huang DT, Clermont G, Kong L, Weissfeld LA, Sexton JB, Rowan KM, Angus DC. *Intensive care unit safety culture and outcomes: a US multicenter study.* Int J Qual Health Care 2010; 22: 151-61.
21. Valentin A, Schiffinger M, Steyrer J, Huber C, Strunk G. *Safety climate reduces medication and dislodgement errors in routine intensive care practice.* Intensive Care Med 2013; 39: 391-8.
22. Katz-Navon T, Naveh E, Stern Z. Safety Climate in Healthcare Organizations: *A Multidimensional Approach.* Academy of Management Journal 2005; 48: 1075-89.
23. Singer S, Lin S, Falwell A, Gaba D, Baker L. *Relationship of safety climate and safety performance in hospitals.* Health Serv Res 2009; 44: 399-421.
24. Sexton JB, Helmreich RL, Neilands TB, Rowan K, Vella K, Boyden J, Roberts PR, Thomas EJ. *The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research.* BMC health services research 2006; 6: 44.

25. Helmreich RL. *Cockpit management attitudes.* Hum Factors 1984; 26: 583-9.
26. Morris JA, Gardner MJ. *Calculating confidence intervals for relative risks (odds ratios) and standardised ratios and rates.* Br Med J (Clin Res Ed) 1988; 296: 1313-6.
27. Sahai H, Kurshid A. *Statistics in epidemiology: methods techniques and applications.* CRC Press, 1996.
28. Thomassen O, Storesund A, Softeland E, Brattebo G. *The effects of safety checklists in medicine: a systematic review.* Acta Anaesthesiol Scand 2014; 58: 5-18.
29. de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boermeester MA, Group SC. *Effect of a comprehensive surgical safety system on patient outcomes.* N Engl J Med 2010; 363: 1928-37.
30. Hamman WR, Beaudin-Seiler BM, Beaubien JM. *Understanding interdisciplinary health care teams: using simulation design processes from the Air Carrier Advanced Qualification Program to identify and train critical teamwork skills.* J Patient Saf 2010; 6: 137-46.
31. Guerlain S, Turrentine B, Adams R. *Using video data for the analysis and training of medical personnel.* Cogn Tech Work 2004; 131–38.
32. Beus JM, Payne SC, Bergman ME, Arthur W. *Safety climate and injuries: an examination of theoretical and empirical relationships.* J Appl Psychol 2010; 95: 713-27.
33. Zohar D. *A group-level model of safety climate: testing the effect of group climate on microaccidents in manufacturing jobs.* J Appl Psychol 2000; 85: 587-96.
34. Sexton JB, Berenholtz SM, Goeschel CA, Watson SR, Holzmueller CG, Thompson DA, Hyzy RC, Marsteller JA, Schumacher K, Pronovost PJ. *Assessing and improving safety climate in a large cohort of intensive care units.* Crit Care Med 2011; 39: 934-9.
35. Paine LA, Rosenstein BJ, Sexton JB, Kent P, Holzmueller CG, Pronovost PJ. *Republished paper: assessing and improving safety culture throughout an academic medical centre: a prospective cohort study.* Postgrad Med J 2011; 87: 428-35.
36. Pronovost PJ, Freischlag JA. *Improving teamwork to reduce surgical mortality.* JAMA 2010; 304: 1721-2.

37. Ricci MA, Brumsted JR. *Crew resource management: using aviation techniques to improve operating room safety.* Aviat Space Environ Med 2012; 83: 441-4.
38. Neily J, Mills PD, Young-Xu Y, Carney BT, West P, Berger DH, Mazzia LM, Paull DE, Bagian JP. *Association between implementation of a medical team training program and surgical mortality.* JAMA 2010; 304: 1693-700.

Figures

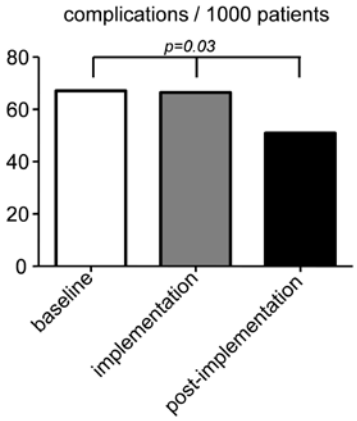


Figure 1
Complication incidence per 1000 patients in the three cohorts.
p-value calculated using Chi-square test.

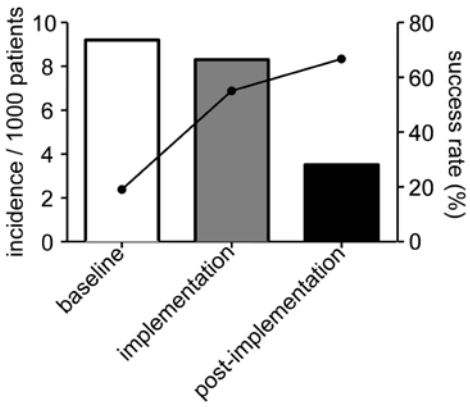


Figure 2
Cardiopulmonary resuscitation incidence (bars) and success percentage (dots/line) in the three cohorts.
Cardiopulmonary resuscitation incidence significantly decreased (p=0.04, Chi-square test) while the success rate significantly increased (p=0.02, Chi-square test).

Tables

Table 1: Patient characteristics

	Baseline year	Implementation year	Post-implementation year	p-value
Number of ICU patients (n)	2295	2423	2553	
Age (yr)	64 (53-73)	64 (53-73)	65 (54-73)	0.12
Female sex, no (%)	818 (35.6)	865 (35.7)	899 (35·.2)	0.93
Weight (kg)	79 (70-89)	78 (69-88)	79 (70-90)	0.14
Height (cm)	172 (165-180)	173 (166-180)	174 (166-180)	0.049
Type of admission				
Medical, no (%)	739 (32.2)	774 (31.9)	842 (33.0)	
Elective surgery, no (%)	1215 (52.9)	1364 (56.3)	1352 (53.0)	0.01
Emergency surgery, no (%)	341 (14.9)	285 (11.8)	359 (14.1)	
Chronic diagnoses				
Chron cardiovascular insuff, no (%)	112 (4.9)	31 (1.3)	83 (3.3)	<0.001
Resp insuff, no (%)	65 (2.8)	45 (1.9)	68 (2.7)	0.07
Chron renal insuff, no (%)	91 (4.0)	86 (3.5)	114 (4.5)	0.26
Chron dialysis, no (%)	28 (1.2)	33 (1.4)	50 (2.0)	0.08
Metastaticsed malignancy, no (%)	78 (3.4)	59 (2.4)	103 (4.0)	0.007
Hematological malignancy, no (%)	70 (3.1)	59 (2.4)	54 (2.1)	0.11
Immunol insuff, no (%)	78 (3.4)	107 (4.4)	135 (5.3)	0.006
AIDS, no (%)	2 (0.1)	5 (0.2)	0 (0)	0.06
APACHE diagnosis group				
Cardiovasc, no (%)	1263 (55.0)	1336 (55.1)	1289 (50.5)	
Gastro-intestinal, no (%)	175 (7.6)	174 (7.2)	211 (8.3)	
Genito-urinary, no (%)	55 (2.4)	59 (2.4)	64 (2.5)	
Hematology, no (%)	16 (0.7)	17 (0.7)	20 (0.8)	
Metabolic, no (%)	19 (0.8)	27 (1.1)	30 (1.2)	0.16
Musculoskeletal/Skin, no (%)	34 (1.5)	43 (1.8)	51 (2.0)	
Neurological, no (%)	301 (13.1)	305 (12.6)	334 (13.1)	
Respiratory, no (%)	295 (12.9)	323 (13.3)	354 (13.9)	
Transplant, no (%)	12 (0.5)	13 (0.5)	21 (0.8)	
Trauma, no (%)	125 (5.4)	126 (5.2)	179 (7.0)	
Mechanical Ventilation in first 24 hrs, no (%)	1932 (84.2)	2071 (85.5)	2059 (80.7)	<0.001
Vasoactive medication, no (%)	992 (43.2)	1184 (48.9)	1000 (39.2)	<0.001
APACHE-IV score	53 (40-69)	63 (48-79)	66 (50-82)	<0.001
APACHE-IV probability score	0.05 (0.01-0.18)	0.07 (0.03-0.22)	0.09 (0.04-0.25)	<0.001
SAPS	34 (27-44)	36 (30-46)	36 (29-46)	<0.001
SAPS probability score	0.15 (0.08-0.33)	0.18 (0.11-0.37)	0.18 (0.37)	<0.001
LODS	5 (4-7)	6 (5-8)	6 (4-8)	<0.001
LODS probability score	0.21 (0.15-0.38)	0.29 (0.21-0.48)	0.29 (0.15-0.48)	<0.001
MPM0	0.11 (0.07-0.22)	0.09 (0.06-0.20)	0.10 (0.06-0.22)	<0.001
MPM24	0.24 (0.14-0.37)	0.25 (0.15-0.37)	0.23 (0.13-0.38)	0.10

Data are presented as median (interquartile range) or number (percentage). p-value calculated by Kruskall Wallis tests or chi-square tests.

Table 2: Complication incidence and outcome parameters

	Baseline year	Implementation year	Post-implementation year	p-value
Number of ICU patients	2295	2423	2553	
Line sepsis	3 (1.3)	7 (2.9)	3 (1.2)	0.29
Ventilator induced pneumonia	1 (0.4)	1 (0.4)	1 (0.4)	1.00
Decubitus (grade III / IV)	20 (8.7)	17 (7.0)	11 (4.3)	0.16
Unplanned extubation (self)	40 (17.4)	46 (19.0)	48 (18.8)	0.91
Unplanned extubation (other)	0 (0.0)	1 (0.4)	1 (0.4)	0.63
Acute myocardial infarction	13 (5.7)	27 (11.1)	23 (9.0)	0.12
Cardiac arrest	21 (9.2)	20 (8.3)	9 (3.5)	0.04
Pneumothorax (iatrogenous)	10 (4.4)	10 (4.1)	10 (3.9)	0.97
CVA (stroke)	1 (0.4)	2 (0.8)	4 (1.6)	0.43
Critical illness polyneuropathy / myopathy	21 (9.2)	12 (5.0)	7 (2.7)	0.01
Difficult intubation*	1 (0.4)	4 (1.7)	3 (1.2)	0.45
Loss of airway	3 (1.3)	0 (0.0)	4 (1.6)	0.17
Early tracheostomy related hemorrhage	5 (2.2)	4 (1.7)	1 (0.4)	0.22
Late tracheostomy related hemorrhage	2 (0.9)	1 (0.4)	1 (0.4)	0.73
Loss of airway during trachea canula related procedure	1 (0.4)	0 (0.0)	0 (0.0)	0.34
Anatomical complications with tracheostomy	1 (0.4)	0 (0.0)	0 (0.0)	0.34
Vascular access problem	6 (2.6)	5 (2.1)	3 (1.2)	0.51
Gastrointestinal bleeding	5 (2.2)	4 (1.7)	1 (0.4)	0.22
Total no. of complications	154 (67.1)	161 (66.4)	130 (50.9)	0.03
ICU-LOS (days)	1.0 (0.8-3.0)	1.1 (0.8-3.0)	1.0 (0.8-2.8)	0.008
Hosp-LOS (days)	6.7 (3.7-15.2)	6.1 (3.1-13.8)	6.7 (3.5-13.4)	0.09
ICU mortality, no (%)	187 (8.1)	201 (8.3)	211 (8.3)	0.98
SMR	0.72 (95% CI 0.63-0.81)	0.69 (95% CI 0.61-0·78)	0.60 (95% CI 0.53-0.67)	0.04*

Complication data are presented as: incidence (incidence/1000 patients).
ICU-LOS, Hosp-LOS are presented as median (interquartile range). ICU mortality and Hosp mortality are presented as number (percentage).
p-value calculated by Kruskall Wallis test or chi-square test, except for SMR data for which the difference between the baseline and post-implementation year was calculated as described previously.[18,19] * Difficult intubation was defined as more than 3 intubation efforts or an intubation duration of >10 minutes.

Table 3: SAQ scores of ICU professionals

	Before CRM training (n=251)	After CRM training (n=161)	p-value
Stress recognition	43 (0-90)	48 (1-84)	0.12
Teamwork climate	69 (38-90)	76 (38-100)	0.001
Safety climate	64 (29-97)	70 (29-94)	<0.001
Perceptions of management	58 (17-84)	64 (27-84)	<0.001
Working conditions	58 (17-86)	58 (11-90)	0.009
Job satisfaction	69 (43-90)	74 (43-95)	0.04

Data are represented as median (range). p-value calculated by Mann-Whitney U-test. Response before and after CRM training was 72% and 51%, respectively. See Table S1 (Supplemental Digital Content) for SAQ scores per discipline.

Table 4: SAQ scores of ICU professionals per discipline

Medical staff

	Before CRM training (n=25)	After CRM training (n=14)
Stress recognition	51 (22-90)	64 (38-97)
Teamwork climate	76 (62-90)	79 (69-86)
Safety climate	69 (46-97)	76 (55-82)
Perceptions of management	53 (17-74)	64 (27-74)
Working conditions	58 (27-79)	58 (48-79)
Job satisfaction	74 (53-90)	74 (64-84)

Nurses

	Before CRM training (n=204)	After CRM training (n=136)
Stress recognition	43 (0-79)	48 (1-84)
Teamwork climate	69 (38-90)	72 (38-100)
Safety climate	64 (29-88)	70 (29-94)
Perceptions of management	58 (17-84)	64 (27-84)
Working conditions	58 (17-79)	58 (11-90)
Job satisfaction	69 (43-90)	74 (43-95)

Other

	Before CRM training (n=22)	After CRM training (n=11)
Stress recognition	40 (17-74)	40 (17-79)
Teamwork climate	72 (55-83)	76 (69-86)
Safety climate	64 (48-79)	75 (61-82)
Perceptions of management	64 (43-84)	66 (43-74)
Working conditions	56 (38-79)	64 (53-79)
Job satisfaction	74 (53-90)	76 (48-90)

Data are represented as median (range).

Supplemental file

Crew Resource Management (CRM) training content

Training setting:
Two-day (16 contact hours) full time training using lectures, video-feedback and interactive exercises. Training was conducted in a facility outside of the hospital (to minimize interference with daily practice) in multidisciplinary groups of 15 trainees by two trainers. All levels of care providers (attending physicians, nurses, residents, etc.) were required to participate.

Curriculum / training subjects:
Core subject of the training is "Situational Awareness" (SA), defined as the ability to identify, process, and communicate the critical elements of information relevant to the team with regard to the mission. Team SA is considered to be the basis for effective decision making in safety-critical environments and a core competence for any professional team. Threats to SA are called "red flags" (eg, conflicting inputs, preoccupation, lack of communication, confusion, violations of policies or procedures, failure to meet targets or address discrepancies, fatigue, complacency, stress), which indicate an adverse situation and an imminent undesirable event are discussed.

"Human Errors" explains how several error types may develop into incidents. The benefits of effective teamwork in identifying threats and deal with them before they become errors are shown, followed by techniques in preventing and counteracting the effects of errors. The use of a comprehensive framework of standard operating procedures (SOP) and checklists is also discussed. Goal is to adopt a credible, non-punitive policy toward human error (not violations).

"Communication" explains CRM team communication principles and describes how to execute them. Trainees learn the components of a

cross-check (monitor the situation, recognize red flags, communicate red flags precisely, and follow up with feedback) and practice effective assertive statements that command attention, convey concern, state the problem, and propose a solution. Trainees learn how to perform productive briefings before critical team activities.

"Performance feedback" focuses on professional assertiveness and per- and post event feedback.
Per-event feedback starts with careful consideration of timing and relevance of the message, followed by 3 levels of performance feedback. The first level requires the team member to formulate the message short, clear and non-blaming ("doctor/nurse, I'm not sure we did all the checks…"). The second level contains a key word that has a defined value ("doctor/nurse, I'm not comfortable with that decision…"). If this feedback is ignored, and the situation is considered unacceptable the last resort could be a request to "stop the procedure", including eye contact and e.g. touching the arm of the person performing the procedure.
Post event feedback (or debriefing) is defined as a structured conversation in which individuals describe the plan versus the outcome, their thoughts about what transpired, and what they plan to do differently should a similar situation recur.

"Management of stress, workload and fatigue" addresses signs, symptoms, and causes of stress, fatigue, and circadian rhythms, and explains how disruptive these factors may be to human performance. Coping strategies are discussed.

"Creating and maintaining team structure and climate" introduces trainees to behavioral group dynamics and how to recognize and counteract negative group tendencies.

"Leadership" focuses on the impact of leader- and follower roles on team effectiveness. Hospital professionals learn to appreciate the difference

between technical capabilities and leadership skills. This element shows the gains of effective leadership and provides practical do's and don'ts. "Risk management and decision making" trains participants to balance the criticality of a decision against its time urgency by a systematic approach. This makes explicit the value of shared mental models in team decision-making.

In summary, CRM training teaches team behavioral strategies with lectures and interactive sessions. Training enables participants to recognize how the skills enhance performance of individuals and teams by leveraging all knowledge and abilities present in the team.

To be effective as a culture intervention the CRM training phase is part of a multi-stage effort including implementation support, as we have published previously.[E1]

Reference

E1. Haerkens MH, Jenkins DH, van der Hoeven JG. Crew resource management in the ICU: the need for culture change. Ann Intensive Care 2012; 2(1):39.

Chapter 5

Impact of CRM in the Trauma Room

Crew Resource Management in the Trauma Room: a prospective three-year cohort study

MHTM Haerkens
PM Noe
M Kox
JG van der Hoeven
P Pickkers

Provisionally accepted for publication in Eur J Emerg Med

Abstract

Objective

Human Factors account for the majority of adverse events. Human Factors awareness training entitled Crew Resource Management (CRM) is associated with improved safety and reduced complications and mortality in critically ill patients. We determined the effects of CRM implementation in the Trauma Room of an Emergency Department (ED).

Methods

A prospective three-year cohort study was performed in a level 1 ED, admitting >12,000 patients annually (>1500 trauma-related). At the end of the baseline year, CRM training was performed, followed by an implementation year. The third year was defined as clinical effect year. The primary out-comes were safety climate, measured using the Safety Attitudes Questionnaire (SAQ) and ED length of stay. Secondary outcome measures were hospital length-of-stay, and 48-hour crude mortality of trauma patients.

Results

All 5070 trauma patients admitted to the ED during the study period were included. Following CRM implementation, safety climate significantly improved in 3 out of 6 SAQ-domains, both at the end of the implementation and clinical effect years: teamwork climate, safety climate, and stress recognition. ED length-of-stay of these patients increased from 141 [102-192] in the baseline year to 161 [116-211] and 170 [128-223] minutes in the implementation and clinical effect years, respectively ($p<0.05$ vs. baseline). Hospital length-of-stay was prolonged by 1 day in the implementation and clinical effect years ($p<0.05$ vs. baseline), while mortality was unaltered.

Conclusions

Although CRM-implementation in the ED was associated with an improved safety climate, the time spent by trauma patients in the ED increased.

Introduction

Background

Human Factors refer to environmental, organizational and job factors, and to human and individual characteristics which influence professional behaviour in a way that affects performance, safety and human well-being.[1] As Human Factors account for the majority of adverse events in aviation, all aircrew receive Human Factors awareness training entitled 'Crew Resource Management' (CRM).[2] During the implementation of aviation CRM since 1979, a concordant decrease in events led to CRM becoming the present day operational standard.[3, 4] CRM is deemed vital for aircrew performance, especially during time-critical emergencies. CRM uses a system approach to safety culture that focuses on identifying system flaws rather than individual failure[5, 6] to achieve a "just culture": a professional environment in which front-line operators and others are not punished for actions, omissions, or decisions taken by them which are commensurate with their experience and training, but where gross negligence, willful violations, and destructive acts are not tolerated.[7]

Human factors also appear to impact team performance and patient safety in clinical medicine.[8-10] Human error, if not mitigated, often leads to cycles of error and unintended patient states, which are dangerous and precede the majority of harmful outcomes.[11] Therefore, it appears plausible that especially departments where high risk, time-critical procedures are performed in a multidisciplinary team setting are likely to benefit from CRM.[11, 12] On the other hand, the effect of implementation of CRM on workflow and time spent per patient are currently unknown.

Importance

Our previous study in critically ill patients showed that implementation of the CRM-team format is indeed associated with a positive impact on safety climate, a reduction in serious complications, and lower mortality.[13]

Caring for trauma patients in the often hectic and chaotic setting of an Emergency Department (ED) is prone to error because of a number of

organizational and human factors. Time-critical decisions made by multiple health care professionals and consultants, frequent workflow interruptions, numerous hand-offs of care, reliance on verbal orders, and shiftwork-induced provider fatigue all contribute to a challenging environment for a healthcare team to perform effectively and safely.[14-16]

Goals of this investigation

The primary aim of this study was to assess the effects of CRM-implementation on safety climate and time spent in a Dutch level 1 Trauma Center's Emergency Department. Furthermore, we assessed the effects of CRM implementation on hospital length-of-stay and 48-hour crude mortality of trauma patients.

Methods

Study design and setting

A unit-wide CRM intervention was implemented in the ED and analyses of its effects in the Trauma Room were planned prospectively. As the nature of the intervention (training phase followed by 1 year with a multitude of implementation efforts) limited the possibilities of performing a study using a control arm, a pre-during-post implementation design was chosen and a 'baseline year', 'implementation year', and 'clinical effect year' were designated.

CRM was implemented in the ED of the Isala hospital, a 978 bed teaching hospital with approximately 47,000 admissions annually. The ED treats around 35,000 patients yearly, including approximately 1600 trauma patients.

Selection of Participants

Isala's ED workforce (in FTE's) includes 7 emergency physicians, 16 residents, and a nursing staff of 53. All ED personnel, 5 (out of 7) attending trauma surgeons and 6 (out of 40) anesthesiologists participated in the CRM-training. The independent aerospace training organization that provided

the CRM-training consisted of 9 trainer/coaches (senior military and commercial airline pilots, psychologists, and medical specialists, some of which are dual-qualified). All were proficient in the area of operational human factors as well as CRM development and training.

Interventions

At the end of the baseline year, all ED personnel received two consecutive days (8 contact hours per day) of human factors awareness training in multidisciplinary groups of 15 participants. All training sessions were conducted within a short (two-month) window to maximize impact and were held at a training facility at some distance to the hospital to minimize interference. The training curriculum was developed from aviation CRM-standards and adapted to clinical healthcare by the training organization, included lectures on human factors and CRM principles, multiple team exercises, and interactive sessions using realistic data such as case studies and video footage from the ED.

Key areas of the CRM-training included situational awareness and recognition of adverse situations, human errors and non-punitive response, communication and briefing and debriefing techniques, providing and receiving performance feedback, management of stress, workload and fatigue, creating and maintaining team structure and climate, operational leadership, and risk management and decision-making (see[17] for more detailed information on the training curriculum). Each training resulted in a shortlist of practical "action points" to be realized in the following implementation year (for example standardized briefings, debriefings and handover during patient admission and transfer, checklists for common ED procedures such as endotracheal intubation, and noise/static reduction methods).

As implementation of Human Factors principles into daily practice is challenging and relies heavily on clinical ownership and extensive follow-up[12], a multidisciplinary "CRM Core Group" was formed to coordinate and monitor the implementation efforts. This Core Group consisted of 2 emergency physicians, 3 ED nurses, 2 trauma surgeons, 1 anesthesiologist,

1 anesthesiology technician, and a CRM-instructor in a coaching capacity. Their mission was to create professional ownership by translating the CRM action points into useable tools for clinical practice and interface regularly with the department's medical, nursing and management staff. During the implementation year two modalities of additional training were provided. First, to establish the lessons learnt from CRM training within daily clinical practice, scenario-based team training was conducted. This simulation was conducted 2-3 times a week on site, using basic simulation manikins and CRM-trained clinical supervisors. As with the CRM-training, the scenario based team training used a multidisciplinary setting and involved the majority of the ED staff (participation of surgeons and anesthesiologists/ ICU consultants was limited). Second, to prevent "dilution" of Human Factors awareness, all new personnel (5 nurses, 5 residents and 2 emergency physicians during the period of study conduct) received the regular two-day CRM training.

Methods and Measurements

Patient clinical outcome data were collected from the Dutch National Trauma Registry (NTR) database.[18] The NTR was developed in 2004 by the Dutch Trauma Society and every trauma center is responsible for supplying all trauma data to the NTR. To prevent incorrect (e.g. double) registration the data were subsequently checked by the ED's database manager and rechecked by the national Trauma Registry organization. Data were encrypted by the removal of all patient-identifying information. The National Trauma Registry initiative is officially registered in accordance with the Dutch Personal Data Protection Act. The study was carried out in accordance with the applicable rules concerning the review of research ethics committees and informed consent. Data collection was standardized according to strict definitions and was subject to stringent quality checks.

Data was collected during the baseline year preceding the two-month CRM training phase (November 2011 until the end of October 2012), the implementation year following the training phase (January 2013 until the

end of December 2013), and the clinical effect year (January 2014 until the end of December 2014).

Outcomes

The primary outcome measure was the effect of CRM implementation on perceived safety climate and time spent in the ED. As evidence from non-clinical[19] and clinical[20-23] critical environments indicate a positive relationship between safety climate and safety outcome, we measured the ED's safety climate at the end of all three study periods. Safety climate was determined by the Safety Attitudes Questionnaire (SAQ). The SAQ is a validated health-care derivative of the Cockpit Management Attitudes Questionnaire, and responsive to interventions.[20, 24-26] All CRM participants were invited to fill out an online Dutch translation of the SAQ (SAQ-NL, described in Chapter two of this thesis) at end of the baseline, implementation and clinical effect year. Secondary outcome measures were hospital length-of-stay, and mortality.

Analysis

Kruskall Wallis tests with Dunn-Bonferroni post-hoc tests were used to compare continuous data between the three groups. Chi-square tests were used to compare proportions. In addition, univariate multiple linear regression analysis was performed using age and injury severity score (ISS) as covariates. Data were analyzed using SPSS Statistics 22 (IBM Corp., Armonk, NY, USA) and Graphpad Prism 5.0 (Graphpad Software, La Jolla, USA).

Results

Safety climate assessment

Response rates for the three online questionnaires were 86%, 54% and 83% after baseline, implementation and clinical effect year, respectively. Following CRM implementation, perceived safety climate significantly improved in 3 out of 6 Safety Attitudes Questionnaire-domains both at the end of the implementation and clinical effect year: teamwork climate, safety

climate and stress recognition (Figure 1). Job satisfaction and working conditions scores did not change. Perceptions of management scores showed a decreasing trend at the end of the implementation year, and were significantly lower at the end of the clinical effect year compared with baseline.

Patient data

The three cohorts consisted of 1772 (baseline year), 1614 (implementation year), and 1684 (clinical effect year) trauma patients, including severe trauma patients delivered by Helicopter Emergency Medical Services (HEMS) 36 (baseline year), 32 (implementation year), and 40 (clinical effect year). During the three-year study period, no relevant changes in staffing levels, device use, or protocols/procedures occurred, except for the ED moving to another location in the hospital in August 2013.

Patient characteristics are listed in Table 1. Age was higher in the implementation year compared with the baseline year. Although median levels were similar, the injury severity score (ISS) was significantly higher in the clinical effect year compared with baseline.

Time spent in the ED was almost 20 minutes and almost 30 minutes longer during the implementation and clinical effect year, respectively.

Furthermore, hospital length-of-stay was higher in the implementation and clinical effect years compared with baseline, while crude early mortality (within 48 hours after admission) was not different between the study periods.

After adjusting for age and ISS, ED and hospital length of stay remained significantly higher in the implementation and post-implementation years compared with the baseline year (ED length of stay: B [95% CI]: $15^{10\text{-}21}$ and 27 [22-32], respectively, both $p<0.0001$; hospital length of stay: B [95% CI]: 0.9 [0.4-1.4] and 1.0 [0.5-1.5], respectively, both $p<0.0001$).

Discussion

This study demonstrates an association between CRM implementation in the ED and an improved perceived safety climate, but also with a prolonged length-of-stay of trauma patients at the ED. Several factors may explain the positive effects of CRM implementation on perceived safety climate in the present study. First, the introduction of CRM was not limited to a single training effort, but comprised a myriad of activities to create professional ownership.[6]

The action points, formulated during all training sessions and based on CRM core items, were molded into the new way of professional interaction within the ED by a core group of ED-professionals under additional coaching from a CRM-instructor during the implementation year. Furthermore, to secure the CRM lessons learned in daily practice, scenario-based team training was conducted during the implementation year[17, 27], an annual "week of CRM" was introduced, and team performance became a standard item in staff meetings. Second, CRM-training and implementation support was conducted by instructors with credible operational experience in clinical medicine, aviation, and cognitive psychology. As, in contrast to aviation, medical CRM has no accepted standard yet, this helped convince clinical professionals of the potential gains of CRM and allow this new professional and team identity into the ED. Third, to prevent dilution of Human Factors awareness CRM training was provided not only during the initial training period, but also to new staff during the later study periods. Finally, as the ED was the first department in the hospital that aimed to adopt Human Factors principles, firm commitment and endorsement from the department's manager and lead ED physician was instrumental throughout the intervention.[6, 17]

Safety climate is positively related to safety outcomes in high-hazard working environments, including the high-risk clinical arenas.[21, 30, 31] In previous clinical studies on the impact of improved safety climate on outcome, team training was associated with improved safety climate[26, 32, 33],

patient outcome[34], or both.[13] Importantly, the number of studies that determined both safety climate and clinical outcome is limited to only one. Clinical CRM implementation in has also been associated with a reduction of malpractice expenses, reported to be as high as 62% in an obstetric environment.[35] One study in the operating room of an academic center even showed a dramatic cost reduction from $ 793,000 to zero.[36] To date, no prospective randomized trials evaluating the impact of CRM in the trauma room have been published. Interestingly, in contrast with improving overall SAQ-scores, the perceptions of management domain showed a decreasing trend. This may be indicative of the challenge that, as the clinically-led CRM-initiative gained momentum and awareness of Human Factors-related issues increased, managerial limitations to implementation of CRM action points emerged. CRM training may result in more safety awareness and a more critical appraisal of health care providers towards their management. As Paine et al described[26], the clinician's concern about managerial work may present an obstacle to the implementation of human factors principles in healthcare.

Evidence the impact of CRM on mortality is still scarce, and results vary.[13, 37] In the present study, no effect on crude mortality was found. This is not surprising in view of the statistical power of the study and may be explained by the low mortality rate in our patient group with a mild overall ISS of 9. As previous studies of patients with mild trauma injury have shown, impacting mortality would require much larger cohorts than the present study.[38] Our study was underpowered to demonstrate an effect of CRM implementation on outcome in the subgroup with a higher ISS. Hospital length-of-stay was significantly increased in the implementation and clinical effect years. We do not have an explanation for this observation and no factors linking our intervention to increased hospital length of stay were identified. ED length-of-stay was higher in the implementation and clinical effect years compared with baseline. In our view it is plausible that this is the result of CRM-implementation, as more stringent use of procedures and checklists may take more time. So, while thorough use of procedures and checklists

has benefits[39], it may be more time-consuming. Although the current study provides no causal evidence linking CRM implementation to improved outcome, we support more widespread implementation of Human Factors awareness training in the high-risk ED environment. An interesting parallel, in aviation CRM became the present day operational standard due to the perceived impact on safety climate and aircrew effectiveness, especially during time critical cockpit emergencies, even though scientific evidence is still lacking. As the initial care for trauma patients in most level 1 ED's adheres to the same treatment principles, our findings are likely to be generalisable to other international EM settings with comparable levels of patient activity. The current study has several limitations, two of which concern our study design. Most importantly, this is a non-randomized single-centre study. The intensity and duration of the training as well as the implementation process importantly limit the feasibility of using other study designs. Additionally, the fact that the safety climate assessment relied on anonymous completion of questionnaires did not allow for a individually paired analysis of the results. In spite of both these design limitations, we believe that it is plausible that the improved safety climate is related to the CRM intervention. Furthermore, the Safety Attitude Questionnaire's response rate after implementation was relatively low. While low response rates may increase the risk of a non-response bias, results from "low" response-rate surveys may still accurately represent attitudes of the population.[28] This appears to be the case in the current study as well, as the last SAQ-measurement (following the clinical effect year), which resulted in an adequate response rate, showed a continuation of the previous trend.

An important success factor for culture interventions is a stable, intact team.[29] As the ER is not a closed-format department and must respond to emergencies that require a broad spectrum of specialist expertise, maintaining a stable team is not possible, as ad hoc participation of physicians other than those of the trauma team is frequently required. In our setting, it proved challenging to make every professional with responsibilities in the ER beyond the ER- and trauma staff (e.g. anesthesiologists and trauma

surgeons) participate in CRM-training. This may have limited the impact of our intervention. Finally, the ED moving to another location in the hospital during the CRM-implementation phase may have confounded our results, even though no relevant changes in procedures, staffing levels, technical infrastructure, or other major changes that could influence patient management took place. The fact that the SAQ-domain of 'working conditions' showed no significant change over time supports that this was not a major factor.

In conclusion, our study demonstrates that CRM implementation at the ED is associated with an improved perceived safety climate at the expense of a longer ED length-of-stay for trauma patients.

Acknowledgements

The authors would like to thank Erik Lely for data extraction from the SAQ database and Danique Hesselink for extracting data from the National Trauma Registry.

References

1. Dempsey PG, Wogalter MS, Hancock PA. *Defining ergonomics/human factors.* W Karwowski (Ed) International Encyclopedia of Ergonomics and Human Factors (Second Edition), London: Taylor and Francis. 2006;32-5.
2. Cooper GE, White MD, Lauber JK. *Resource management on the flightdeck: proceedings of a NASA/industry workshop.* NASA-Ames Research Center Moffett Field: NASA CP-2120; 1980.
3. Commission Regulation (EU) No 965/2012, chapters ORO.FC.115: *Crew resource management (CRM) training, and ORO.FC.215: Initial operator's crew resource management (CRM) training.*
4. FAA Part 121: *Operating Requirements: Domestic, Flag, and Supplemental Operations,* article §121.404 Compliance dates: Crew and dispatcher resource management training.
5. Flin R, Maran N. *Identifying and training non-technical skills for teams in acute medicine.* Quality & safety in health care. 2004;13 Suppl 1:i80-4.
6. Leonard M, Graham S, Bonacum D. *The human factor: the critical importance of effective teamwork and communication in providing safe care.* Qual Saf Health Care. 2004;13 Suppl 1:i85-90.
7. European Commission Regulation No. 691/2010. http://eur-lexeuropaeu/LexUriServ/LexUriServdo?uri=OJ%3AL%3A2010%3A201%3A0001%3A0022%3AEN%3APDF].
8. Brindley PG. *Patient safety and acute care medicine: lessons for the future, insights from the past.* Crit Care. 2010;14:217.
9. Kohn LT, Corrigan JM, Donaldson MS. *To err is human: building a safer health system.* Washington: National Academy Press; 2000.
10. Garrouste-Orgeas M, Timsit JF, Vesin A, Schwebel C, Arnodo P, Lefrant JY, et al. *Selected medical errors in the intensive care unit: results of the IATROREF study: parts I and II.* Am J Respir Crit Care Med. 2010;181:134-42.
11. Hickey EJ, Nosikova Y, Pham-Hung E, Gritti M, Schwartz S, Caldarone CA, et al. *National Aeronautics and Space Administration "threat and error" model applied to pediatric cardiac surgery: error cycles precede approxi-mately 85% of patient deaths.* J Thorac Cardiovasc Surg. 2015;149:496-505; discussion -7.
12. Timmons S, Baxendale B, Buttery A, Miles G, Roe B, Browes S. *Implementing human factors in clinical practice.* Emerg Med J. 2015;32:368-72.

13. Haerkens MH, Kox M, Lemson J, Houterman S, van der Hoeven JG, Pickkers P. *Crew Resource Management in the Intensive Care Unit: a prospective 3-year cohort study.* Acta Anaesthesiol Scand. 2015;59:1319-29.
14. Reason JT. *Human Error.* Cambridge University Press, New York. 1990.
15. Joffe MD. *Emergency department provider fatigue and shift concerns.* Clin Pediatr Emerg. 2006;7:248–54.
16. Morey JC, Simon R, Jay GD, Wears RL, Salisbury M, Dukes KA, et al. E*rror reduction and performance improvement in the emergency department through formal teamwork training: evaluation results of the MedTeams project.* Health Serv Res. 2002;37:1553-81.
17. Haerkens MH, Jenkins DH, van der Hoeven JG. *Crew resource management in the ICU: the need for culture change.* Ann Intensive Care. 2012;2:39.
18. Arts D, de Keizer N, Scheffer GJ, de Jonge E. *Quality of data collected for severity of illness scores in the Dutch National Intensive Care Evaluation (NICE) registry.* Intensive Care Med. 2002;28:656-9.
19. Cooper MD, Phillips RA. *Exploratory analysis of the safety climate and safety behavior relationship.* J Safety Res. 2004;35:497-512.
20. Huang DT, Clermont G, Kong L, Weissfeld LA, Sexton JB, Rowan KM, et al. *Intensive care unit safety culture and outcomes: a US multicenter study.* Int J Qual Health Care. 2010;22:151-61.
21. Valentin A, Schiffinger M, Steyrer J, Huber C, Strunk G. *Safety climate reduces medication and dislodgement errors in routine intensive care practice.* Intensive Care Med. 2013;39:391-8.
22. Katz-Navon T, Naveh E, Stern Z. *Safety Climate in Healthcare Organizations: A Multidimensional Approach.* Academy of Management Journal. 2005;48:1075-89.
23. Singer S, Lin S, Falwell A, Gaba D, Baker L. *Relationship of safety climate and safety performance in hospitals.* Health Serv Res. 2009;44:399-421.
24. Sexton JB, Helmreich RL, Neilands TB, Rowan K, Vella K, Boyden J, et al. *The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research.* BMC Health Serv Res. 2006;6:44.
25. Helmreich RL. *Cockpit management attitudes.* Hum Factors. 1984;26:583-9.
26. Paine LA, Rosenstein BJ, Sexton JB, Kent P, Holzmueller CG, Pronovost PJ. *Republished paper: assessing and improving safety culture throughout an academic medical centre: a prospective cohort study.* Postgrad Med J. 2011; 87:428-35.

27. Hamman WR, Beaudin-Seiler BM, Beaubien JM. *Understanding interdisciplinary health care teams: using simulation design processes from the Air Carrier Advanced Qualification Program to identify and train critical teamwork skills.* J Patient Saf. 2010;6:137-46.
28. Meterko M, Restuccia JD, Stolzmann K, Mohr D, Brennan C, Glasgow J, et al. *Response Rates, Nonresponse Bias, and Data Quality. Results from a National Survey of Senior Healthcare Leaders.* Public Opin Q. 2015;79:130-44.
29. Salas E, DiazGranados D, Klein C, Burke CS, Stagl KC, Goodwin GF, et al. *Does team training improve team performance? A meta-analysis.* Hum Factors. 2008;50:903-33.
30. Beus JM, Payne SC, Bergman ME, Arthur W. *Safety climate and injuries: an examination of theoretical and empirical relationships.* J Appl Psychol. 2010;95:713-27.
31. Zohar D. *A group-level model of safety climate: testing the effect of group climate on microaccidents in manufacturing jobs.* J Appl Psychol. 2000;85:587-96.
32. Sexton JB, Berenholtz SM, Goeschel CA, Watson SR, Holzmueller CG, Thompson DA, et al. *Assessing and improving safety climate in a large cohort of intensive care units.* Crit Care Med. 2011;39:934-9.
33. McCulloch P, Mishra A, Handa A, Dale T, Hirst G, Catchpole K. *The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre.* Qual Saf Health Care. 2009;18:109-15.
34. Pronovost PJ, Freischlag JA. *Improving teamwork to reduce surgical mortality.* JAMA. 2010;304:1721-2.
35. Pratt SD, Mann S, Salisbury M, Greenberg P, Marcus R, Stabile B, et al. *Impact of CRM–Based Team Training on Obstetric Outcomes and Clinicians' Patient Safety Attitudes.* The Joint Commission Journal on Quality and Patient Safety. 2007;33:720-5.
36. Ricci MA, Brumsted JR. *Crew resource management: using aviation techniques to improve operating room safety.* Aviat Space Environ Med. 2012;83:441-4.
37. Kemper PF, de Bruijne M, van Dyck C, So RL, Tangkau P, Wagner C. *Crew resource management training in the intensive care unit. A multisite controlled before-after study.* BMJ quality & safety. 2016.
38. Hondo K, Shiraishi A, Fujie S, Saitoh D, Otomo Y. *In-hospital trauma mortality has decreased in Japan possibly due to trauma education.* Journal of the American College of Surgeons. 2013;217:850-7 e1.
39. de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, et al. *Effect of a comprehensive surgical safety system on patient outcomes.* N Engl J Med. 2010;363:1928-37.

Tables

Table 1
Patient characteristics and clinical outcome

	baseline year	implementation year	clinical effect year	p-value
Number of patients	1772	1614	1684	
Age (years)	55 (23-76)	59 (28-79)*	57 (25-79)	0.007
Female sex	822 (46.4)	778 (48.2)	787 (46.7)	0.54
ISS	9 (4-9)	9 (4-9)	9 (4-9)*	0.006
ED LOS (minutes)	141 (102-192)	161 (116-211)*	170 (128-223)*	<0.0001
Hospital LOS (days)	2 (1-7)	3 (2-8)*	3 (2-9)*	<0.0001
Mortality within 48 hours	21 (1.2)	21 (1.3)	33 (2.0)	0.13

Data are presented as median (interquartile range) or number (percentage).
p-values were calculated using Kruskall Wallis tests or chi-square tests.
* indicates $p<0.05$ compared with baseline year (calculated using Dunn-Bonferroni post-hoc tests).
ISS: Injury severity score; ED: emergency department; LOS: length-of-stay.

Figures

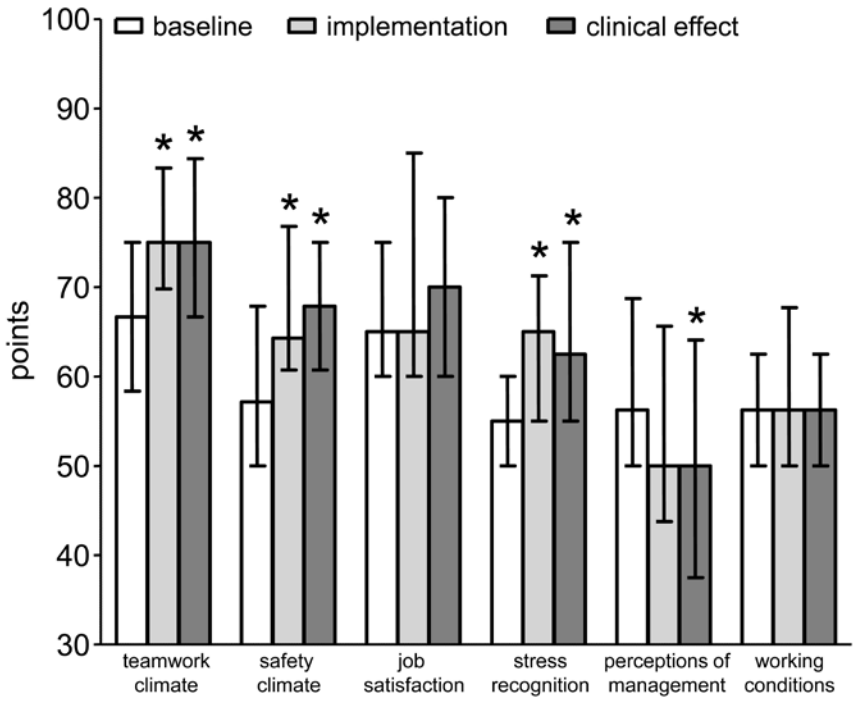


Figure 1
SAQ scores in the baseline, implementation, and clinical effect years

Data are represented as median ± interquartile range. * indicates $p<0.05$ compared with baseline year (calculated using Kruskall Wallis tests followed by Dunn-Bonferroni post-hoc tests).

Chapter 6

Implementation experience and challenges

6.1
A Longitudinal Study on the Effect of Crew Resource Management on Safety Climate in Healthcare

MHTM Haerkens
W van Leeuwen
M Kox
P Pickkers
JG van der Hoeven

PP and JGvdH share senior authorship.

Submitted for publication

Abstract

Background

Human factors account for the majority of adverse events in both aviation and medicine. We determined whether implementation of a Human Factors awareness training entitled "Crew Resource Management (CRM)" is associated with improved safety climate.

Methods

An observational 6-year study in 19 critical clinical departments in three university and seven teaching hospitals in the Netherlands that participated in a CRM intervention.

To assess changes in safety climate, all personnel were invited to fill out the Safety Attitudes Questionnaire (SAQ-NL) before the CRM-training (baseline measure, n=1412), one year after receiving CRM training (post-implementation measure, n=558), and two years after training (follow-up measure, n= 270).

Furthermore, factors for successful CRM implementation were analyzed and we evaluated points for improvement healthcare professionals wanted to implement after receiving initial CRM training, and possible existing barriers to transfer of the CRM training to the work floor.

Results

The overall response rates averaged 68.7%, 41.0% and 77.7%, respectively. There was a positive effect of CRM training on all six SAQ-NL domains over time ($p<0.001$), with a medium effect size.

The success factors 'strong clinical leadership' and 'participation of 90-100% of managers in the training' were associated with a positive effect on the Perceptions of Management domain. The availability of a complication registration was associated with improved Working Conditions domain scores. Furthermore, integration of simulation training into CRM implementation was related to improvements in Safety Climate, Perceptions of Management, and Working Conditions domains.

The results from points for improvement and process observations revealed that clinical professionals perceive the need for mandatory (de)briefings and more structured patient handovers, as well as improved individual leadership/followership and performance feedback skills.

Conclusion

Our data indicate an association between CRM implementation and an improved safety climate, and we identified factors that are important for successful CRM implementation. This could facilitate further optimization of healthcare CRM implementation, and increase awareness of possible barriers.

Introduction

To err is human

Medical error is estimated to be the third leading cause of death in the United States with over 250,000 patients having died as a result of preventable adverse events in 2013. The actual numbers may even be higher because underreporting is likely, as standardized root cause analysis, reporting of inpatient deaths and national data sharing is limited.[1] Beyond the psychological impact on the bereaved and the professionals involved, the financial costs due to these errors are estimated to range between $17 and $29 billion per year in the United States.[2]

Human Factors awareness

Although some medical errors can be attributed to technical malfunctions and failing equipment, many may find their roots in Human Factors (HF). It may therefore be reasonable for the healthcare community to improve HF awareness. An example of a mature HF awareness training curriculum, entitled Crew Resource Management (CRM), originated in the aviation domain. CRM was first introduced in a NASA workshop following research on the contribution of HF in aviation accidents.[3] From there on, CRM evolved 'on the fly'.[4] Currently, CRM revolves around the premise that human error is unavoidable and that error is a source of valuable information. The intent is to be aware of human performance limits, to avoid error or trap errors in an early stage, and to mitigate the consequences of errors that do occur. CRM utilizes communication tools to improve process effectiveness and safety. Aviation has very clear guidelines on CRM training content and frequency of recurrency training. Compliance with these guidelines is a license and currency requirement.[5, 6]

Safety Culture

Safety culture is defined as "the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's

health and safety management".[7] CRM aims to achieve a "just" rather than a "no-blame" safety culture. Although the term no-blame[8] is often associated with CRM, it implicates that individuals should never be blamed. Just culture is based on the assumption that no complex system can be entirely flawless, but gross negligence or substandard performance should be reprimanded and individual professionals held accountable for their actions.[9,10]

Safety Climate

As safety culture is only measurable by careful, long-term observations, it may be more appropriate to use the term safety climate.[11] Safety climate refers to current employee beliefs, perceptions, and attitudes concerning safety and may be measured through questionnaires[11], of which the Safety Attitudes Questionnaire (SAQ) is a validated and widely used example for healthcare.[12, 13]

CRM in healthcare

Each healthcare professional carries the responsibility to operate competently, safely and in the best interest of the patient. However, as safe care relies on the interdisciplinary performance of a care team as much as on individual expertise, improving safety climate may result in a sound basis for better patient outcomes.[14] Since the 1990's, CRM has been implemented in healthcare.[3, 15, 16] As a standard for medical CRM is still lacking, CRM-training comes in various guises. Even though this makes comparing studies on CRM in healthcare challenging, most publications suggest that CRM may be beneficial for safety climate in medical care. Positive effects were found on clinical error rate[17], team climate, safety climate, stress recognition[18], technical and non-technical skills, efficiency[19], team behavior and communication[20], and serious complications and mortality.[21] While most participants evaluate the CRM-training positively, organizational barriers to implementation[22], compliance issues[23], and challenges in transfer of learned behaviours to the job[24] have been identified.

Aims of this study

The aim of the current study was to evaluate the effect of a CRM intervention on safety climate in multiple departments in several Dutch hospitals. Furthermore, we performed an explorative analysis to identify factors associated with successful implementation. The development of safety climate was assessed over a two-year period after training to provide reference for recurrency training schedules.

Finally, we explored which safety measures healthcare professionals want to implement after receiving initial CRM training and possible existing barriers to transfer of training to the work floor. This could provide future CRM trainers, trainees, and policy makers with context specific information on how to further optimize implementation of healthcare CRM, and increase awareness of possible barriers.

Methods

Participants

Participants were recruited at 19 critical clinical departments in three university and seven teaching hospitals in the Netherlands that participated in a CRM intervention. Questionnaire data was collected pre-training (baseline survey), one year post-training (post-implementation survey), and two years post training (follow-up survey) in the period from October 2010 to September 2016. Although only baseline and post-implementation questionnaires were part of the intervention, departments were asked if they were willing to participate in an additional follow-up survey one year later. Participants' needs for change were investigated by analyzing lists that comprised improvement points suggested by trainees during CRM training. Additionally, five departments were invited to participate in process observations in January and February 2016.

CRM intervention

The CRM-intervention consisted of a preparation phase, a training phase and a subsequent implementation phase.

During the preparation phase, process observations were conducted by a minimum of three CRM trainers on separate occasions to evaluate the department based on CRM items as provided in the training. This also allowed trainers to get a 'feel' for the work environment and to collect examples of work processes.

The training phase consisted of mandatory two consecutive 8-hour CRM training days and was given on an off-site location to minimize interference. Each training was conducted by two trainers in multidisciplinary groups representative of the professional composition in day-to-day work (a typical group consisted of nurses, residents, and attending physicians) and was limited to 15 participants. The independent aerospace training organization that provided the CRM training consisted of six trainer/coaches (senior military and commercial airline pilots, psychologists and clinical consultants, or a combination thereof). All were proficient in the area of operational HF as well as CRM development and training. The core subjects were 'situational awareness', 'human error and non-punitive response', 'communication and performance feedback', 'stress and workload management', 'group processes', and 'leadership'. The training included lectures, video footage, interactive exercises and adverse event case discussions. Please see supplemental file 1 for more detailed info on the training curriculum. Every trained group comprised a list of possible points for improvement on the work floor, based on training content and group discussions. The compilation of the points for improvement formed the basis for the subsequent implementation phase.
The implementation phase started after all training sessions were completed. A "CRM core group" was formed from volunteer trainees. The core group received the compilation of points for improvement from all training sessions and was responsible for the translation of these points into useable clinical tools, thus initiating a change process based on the acquired CRM-knowledge and creating professional ownership. This group interfaced regularly with the department's management team and received coaching from a CRM trainer during one year.

Safety Climate measurement

The Safety Attitudes Questionnaire (SAQ) is a reliable instrument to measure healthcare professionals' attitudes, identifying six safety climate related domains: Teamwork Climate, Safety Climate, Stress Recognition, Job Satisfaction, Working Conditions, and Perceptions of Management (see supplemental file 1 for SAQ domain definitions).[12] Safety climate measurements in this study were performed using a validated Dutch translation of the SAQ (SAQ-NL).[13]

Success factors

A list of seven empiric success factors for implementation, obtained from our past CRM / HF integration projects (25) was compiled before analysis. These factors were: hospital administrator involved, strong clinical leadership supportive of CRM, CRM core group still active after one year, complication registration available, simulation training integrated as follow-up, 90-100% of professionals participated, and 90-100% of operational managers participated. Each department scored a 0 (absent) or a 1 (present) on each of these success factors.

Points for improvement

Every trained group composed a list containing possible points for improvement on the work floor, based on training content and group discussions. A total of 94 of these lists were analyzed. Items were categorized in the respective CRM training subject and categorized to provide an overview within the main category.

Process observations

The additional observations in the current study were performed by a trained observer in one university and three teaching hospitals. The observed departments consisted of three cardiac catheterization labs (CCL) and one operating room (OR). Observations lasted between five and seven and a half hours. Furthermore, when the opportunity arose, employees were asked the question *"After receiving the CRM training, what*

did and did not change in your job?" The main goal of the observations was to identify barriers to implementation of points for improvement.

Data collection

Approximately one month prior to the first training, participants were invited to fill out the SAQ-NL (baseline survey) and provide additional demographic data. When an entire department had received the CRM training, the CRM core group was formed and coached during one year. After this year, participants again received an invitation to fill out the SAQ-NL (post-implementation survey) and provide demographic data. A final invitation was sent two years after receiving the CRM training to departments that volunteered in participating in the third measurement (follow-up survey). The points for improvement from all included CRM interventions were comprised from the lists each CRM core group received. For the process observations, five departments that participated in the CRM intervention were contacted and asked if they were willing to participate in an additional observation. They were informed on the aim of the current study and that the observation would be similar to the observation prior to the CRM training.

Statistical Analysis

Multivariate analysis of variance (MANOVA) was utilized to test the hypothesis that CRM training had a positive effect on safety climate in general, with the measuring moment (baseline, post-implementation, and follow-up) as independent variable and mean score on the six SAQ domains as dependent variables. Separate univariate ANOVA's were performed to analyze the effect of measuring moment on the mean scores of the separate SAQ domains. To test how safety climate changed during the first and the second year, a repeated contrast was utilized. This contrast compares the post-implementation to the baseline measure and the follow-up to the post-implementation. Furthermore,

we performed an explorative analysis using separate univariate ANOVA's to analyze whether the presence of each of the seven success factors moderated the relationship between measuring moment and the mean scores of the separate SAQ domains. Data were analyzed with SPSS 22 (IBM corp., 2013). A p-level of $p < 0.05$ was considered to indicate statistical significance. Furthermore, the following cut-offs were utilized for effect sizes: small effect, Cohen d = 0.2, $\eta_p^2 = 0.01$; medium effect, Cohen d = 0.5, $\eta_p^2 = 0.06$; large effect, Cohen d = 0.8, $\eta_p^2 = 0.14$.

Results

Participants

The sample consisted of 19 departments in the baseline, 12 in the post-implementation, and two in the follow-up measure. In total, 2457, 1750 and 405 professionals were invited to participate in the baseline, post-implementation and follow-up measure, respectively. The overall response rates averaged 68.7%, 41.0% and 77.7%, respectively. After excluding respondents that answered less than 28 of the 30 questions for further analysis, data were obtained from 1412, 558 and 270 participants in the baseline, post-implementation, and follow-up measure, respectively. An overview of participant gender and age, participants per academic and teaching hospital, hospital departments, and professional occupation is provided in Table 1.

Safety climate assessment

The main hypothesis was that CRM would have a positive effect on safety climate measured by SAQ-NL. The MANOVA test indicated that there was a significant effect of measuring moment (baseline, post-implementation, follow-up) across the six SAQ-NL domains, $V = 0.12$, $F(12, 4466) = 22.6$, $p < 0.001$, $\eta_p^2 = 0.06$. This represented a significant overall improvement in safety climate with a medium effect size.

Separate univariate ANOVA's revealed that all six individual SAQ-NL domains improved after CRM implementation: Teamwork Climate, $F(2, 2237) = 53.60$, $p < 0.001$, $\eta_p^2 = 0.05$, Safety Climate, $F(2, 2237) = 53.52$, $p < 0.001$, $\eta_p^2 = 0.05$, Job Satisfaction, $F(2, 2237) = 41.48$, $p < 0.001$, $\eta_p^2 = 0.04$, Stress Recognition, $F(2, 2237) = 16.05$, $p < 0.001$, $\eta_p^2 = 0.01$, Perceptions of Management, $F(2, 2237) = 46.51$, $p < 0.001$, $\eta_p^2 = 0.04$, and Working Conditions, $F(2, 2237) = 36.54$, $p < 0.001$, $\eta_p^2 = 0.03$. Effects on the individual SAQ-NL domains are depicted in Figure 1. Furthermore, the mean scores on the SAQ-NL domains for every measuring moment and the effects sizes for the comparison of baseline vs. post-implementation and post-implementation vs. two year follow-up can be found in Table 2. These results indicate that CRM generally has a positive effect on safety climate both in the implementation and the follow-up year. There were no improvements in Job Satisfaction and Working Conditions in the first year, but Teamwork Climate, Safety Climate, Stress Recognition, and Perceptions of Management all significantly increased. Interestingly, there was a strong improvement on most domains in the follow-up year, except for Stress Recognition, which showed a moderate but statistically significant increase, and Perceptions of Management, which showed a trend towards improvement.

Moderating effects of success factors on safety climate

An explorative analysis was performed to evaluate the moderating effects of success factors on individual SAQ-NL domains. For this analysis, the dataset was limited to departments that provided both a baseline and a post-implementation measurement (the follow-up measure was not utilized). The abovementioned analyses performed on this data subset yielded virtually identical results as those found in the entire dataset (data not shown). To identify the moderating effects of the presence of the success factors, we evaluated the interaction term success factor* measuring moment for each of the seven success factors on each SAQ-NL domain. This analysis revealed that hospital administrator involvement, an active core group after 1 year, and participation of 90-100% of professionals were not related to improved SAQ-NL scores. Strong clinical leadership was

associated with a positive effect on the Perceptions of Management domain ($F(1, 1667) = 18.77$, $p < 0.001$, $\eta_p^2 = 0.011$), and the availability of a complication registration was associated with improved Working Conditions domain scores ($F(1, 1667) = 5.71$, $p = 0.02$, $\eta_p^2 = 0.003$). Integration of simulation training into CRM implementation was related to improvements in Safety Climate ($F(1, 1667) = 5.19$, $p = 0.02$, $\eta_p^2 = 0.003$), Perceptions of Management ($F(1, 1667) = 3.92$, $p = 0.048$, $\eta_p^2 = 0.002$) and Working Conditions domains ($F(1, 1667) = 9.85$, $p = 0.002$, $\eta_p^2 = 0.006$). Finally, participation of 90-100% of managers in the training was associated with improved Perception of Management scores ($F(1, 1667) = 18.24$, $p < 0.001$, $\eta_p^2 = 0.011$). These interaction effects are visualized in Figure 2.

Points for improvement

An overview of most cited points for improvement is provided in Table 3.

Situational Awareness. To enhance Situational Awareness, most groups (83%) suggested implementation of mandatory briefing before and debriefing after a medical procedure to introduce participants, to distribute tasks and roles, to enhance the chances of particular information being shared, to create an opportunity to ask questions, to plan for contingencies, and to evaluate whether the procedure went as planned. 31% Suggested that structuring handover of patients should improve to prevent losing critical information when patients transfer from one department to another.

Communication. The majority of the groups felt the need to lower the barrier of speaking up when patient safety was compromised (64%), or to address wanted and unwanted behavior in a neutral and de-escalating manner (17%). Lowering the communication threshold by addressing a colleague by name should be implemented according to 35%. Reducing noise, for instance by limiting the amount of people attending to a procedure or by banning phones and pagers from procedure rooms, was suggested by 34% of the groups. 27% Found improvement of proper closed-loop communication important to ensure that a receiver interpreted the message as it was intended by a sender, and to ensure that challenges

(e.g. patient date of birth, medication) are communicated as open-ended questions (e.g. "what is your date of birth", "what medication am I administering").

Stress. 23% of the groups found it important to improve the opportunity to discuss traumatic events, such as witnessing death of an infant patient, either with mental health professionals or with colleagues. Furthermore, 16% would find it helpful to be able to share and be aware of personal situations that might influence or limit a colleague's performance.

Group Processes. The main topics concerning Group Processes that were transferred to points for improvement related to conflict and Standard Operating Procedures (SOP). 17% Of the groups suggested reduction of conflict by reducing gossip and promoting to talk with, rather than about each other. Implementing mandatory debriefing was seen as a tool to address differences of opinion or work methods in order to avoid escalation of conflict. 13% Found it useful to formalize assumed working agreements into SOP to reduce briefing times (only non-standard proceedings and particularities are briefed), to increase predictability of behavior, and as a tool for addressing others' wanted or unwanted behavior.

Leadership. The relevance to improve operational Leadership behavior was formulated by 37% of the groups. Especially in multi-disciplinary settings such as an ER, it is not always clear who is in charge. This can result in situations where either nobody feels in charge or multiple team members assuming they are in charge.

Human Error. The main point for improvement (37% of the groups) regarding Human Error was to create a work environment in which people feel safe and have time to share and discuss mistakes and near misses with colleagues so that others can learn from them and future adverse events may be avoided.

Process observations

Several barriers to implementation of CRM on the work floor were observed on individual, team and organizational levels:

First, debriefings were often skipped due to time pressure to get to the next patient. In one case, a nurse stated that they no longer had time to debrief after a nurse position got cut from the team in a reorganization. Another reason for not debriefing was that the team broke up before ending the procedure, for instance when a surgical team left when their part of the procedure was done and the procedure ended with only the anesthesiology team present.
Second, a department had merged with another hospital and now half of the staff had never received CRM training. According to one nurse this resulted in differences in who is open for feedback and criticism, and who is not.
Third, two CRM core groups went dormant. One after increased work pressure due to a reorganization and there was no time to get together on a regular basis. The other shortly after coaching by the CRM trainer ended.
Fourth, following the CRM intervention, there was usually no follow-up training for newly hired staff, either due to a lack of planning or due to budget cuts.
Fifth, CRM is, by its very nature, work place oriented, therefore obtaining and retaining commitment from the department's managers has proved challenging in several hospitals.

Discussion

The main finding of this study is that SAQ-NL measurements showed a significant improvement of all 6 domains in the two years following CRM implementation. Furthermore, our explorative analyses of empiric success factors suggest that especially integration of simulation training is an important determinant of successful CRM implementation. Finally, the large majority of trained professionals indicated that mandatory (de)briefings should become an intrinsic part of critical procedures, as should improved techniques for performance feedback.

The safety climate measurements revealed that 4 out of 6 SAQ-NL domains had improved in the post-implementation measurement, increasing to all SAQ-NL domains in the follow–up measurement. A possible explanation for the further increase of safety climate in the follow up year is that it takes time for a core group to think of, and implement, practical solutions to the 'points for improvement". During the first implementation year professionals see little change on the work floor initially, which may explain the absence of effects on the Job Satisfaction and Working conditions domains in the post-implementation measurement. The second year professionals may notice more changes taking effect and developing into an improved standard of working. Our finding that safety climate is still improving after two years may indicate that a three-year CRM-"refresher training cycle" for all personnel may suffice. Furthermore, the CRM intervention in the current study instigates bottom-up change by having trainees formulate the key issues they wish to address and forming a CRM core group that aims at dealing with these issues. This bottom-up process might heighten feelings of job autonomy, which increases job satisfaction according to the job characteristic model.[26, 27] As perceived organizational support is important for employee safety involvement[28], and the opportunity for CRM training may convey the management's concern for a safe work environment, this may explain the positive impact on Perceptions of Management. The increase in Perceptions of Management decreased in the follow-up year. This may highlight the importance of continuing support of management, especially after the initial intervention ended.[29]

Evaluation of the moderating effects of empiric success factors derived from past CRM / HF integration projects (25) on SAQ-NL domains resulted in the finding that integration of simulation training into CRM implementation was related to improvements in Safety Climate, Perceptions of Management as well as Working Conditions domains. Additionally, our finding that hospital administrator involvement is not associated with improved safety climate outcome fits the notion that CRM implementation should be a bottom-up initiative, and that top-down endorsement may

suffice. The observed association between participation of 90-100% of the department's operational managers and strong clinical leadership with increased Perceptions of Management scores may be explained in part by an increased professional's understanding of the manager's role, but may also have helped managers to adopt the disengaged but supportive stance necessary to facilitate the CRM-initiative. An active core group after 1 year was not related to improved SAQ-NL scores, which may indicate that transferring the responsibility for implementing the "points for improvement" to the regular department's management team might be a viable option in future initiatives. The secondary objectives were to investigate what healthcare professionals themselves want to improve to increase safety and reduce medical error after receiving CRM training (points for improvement), and to explore through observations what possible barriers exist to transfer of training to the work floor. The most important points for improvement that the participants reported were mandatory briefing & debriefing, lowering the threshold for performance feedback, reducing noise levels, improve the discussion after traumatic events, improve and maintain SOP's, address leadership during procedures, and to work towards a non-blaming working environment.
The process observations yielded several barriers to CRM implementation, including perceived time constraints, team breakup, incomplete CRM training, CRM core groups that went dormant due to increased work pressure or lack of initiative, lack of follow-up training of new staff due to lack of planning or budget, and insufficient visible commitment from the department's management. A possible reason for the transfer of training to the work floor to be problematic in some cases could be that CRM training is derived from aviation and has not yet been sufficiently adapted to the medical context.[23,30]

The results from points for improvement and process observations underline the importance of mandatory briefing, debriefing and structured patient handover skills. Furthermore clinical professionals perceive the need for improved leadership/followership and performance feedback

skills. Hospital leaders have a key role in creating a working environment where learning from mistakes or near misses becomes a daily routine. Having hospital leaders participate in CRM-training would be a double-edged sword: they would be more aware of Human Factors and, according to this study, enhance their managerial position to boot.

Limitations

The current observational study has no control group(s) in which repeated SAQ-NL measurements were performed without any intervention. Also, though it yields positive results, the data does not allow an explanation for the exact reasons for these improvements. Furthermore, the SAQ-NL response rate post-implementation was relatively low (41%). While low response rates may increase the risk of a non-response bias, results from "low" response-rate surveys may still accurately represent attitudes of the population.[31]

This appears to be the case in the current study as well, as the third follow-up SAQ-NL measurement, which resulted in an adequate response rate, showed a continuation of the previous trend. The fact that only two hospital departments were represented in the third follow-up measure holds the risk of a survey selection bias, which cannot be excluded.

Future research into the effects of CRM

More longitudinal studies are needed to see when the effects of CRM decline to provide information on when refresher training is appropriate. CRM was suggested to increase autonomy in the introduction but this was not tested. This is a possible avenue for future research to investigate what mechanisms make CRM effective for Job Satisfaction.

Conclusions

This study shows that CRM implementation is associated with an improved perceived safety climate. Furthermore, our explorative analyses suggest that especially integration of simulation training is an important determinant of successful CRM implementation. Finally, mandatory

(de)briefings as intrinsic part of critical procedures and enhanced techniques for performance feedback are considered important points for improved care by health care professionals. Human Factors awareness in healthcare in the Netherlands is still in an immature stage, with efforts aimed at changing the way a clinical department works. Training initiatives are facultative, local, and non-standard. For this to improve a multi-disciplinary CRM-training curriculum should be agreed upon by the medical boards, and made an essential part from undergraduate education upward for all (para)medical professionals.

References

1. Makary MA, Daniel M. *Medical error-the third leading cause of death in the US.* Bmj. 2016;353:i2139.
2. Kohn LT, Corrigan JM, Donaldson MS. *To err is human: building a safer health system*. Washington: National Academy Press; 2000.
3. Cooper GE, White MD, Lauber JK. *Resource management on the flightdeck: proceedings of a NASA/industry workshop*. NASA-Ames Research Center Moffett Field: NASA CP-2120; 1980.
4. Helmreich RL, Merritt AC, Wilhelm JA. *The evolution of Crew Resource Management training in commercial aviation.* Int J Aviat Psychol. 1999;9(1):19-32.
5. Commission Regulation (EU) No 965/2012, chapters ORO.FC.115: *Crew resource management (CRM) training,* and ORO.FC.215: *Initial operator's crew resource management (CRM) training*.
6. FAA Part 121: *Operating Requirements: Domestic, Flag, and Supplemental Operations*, article §121.404 Compliance dates: Crew and dispatcher resource management training.
7. Sorra JS, Nieva VF. *Hospital Survey on Patient Safety Culture.* (Prepared by Westat, under Contract No. 290-96-0004). . AHRQ Publication No 04-0041 Rockville, MD: Agency for Healthcare Research and Quality. 2004.
8. Provera B, Montefusco A, Canato A. *A 'No Blame' Approach to Organizational Learning.* British Journal of Management. 2010;21(4):1057-74.
9. Wachter RM, Pronovost PJ. *Balancing "no blame" with accountability in patient safety.* The New England journal of medicine. 2009;361(14):1401-6.
10. Khatri N, Brown GD, Hicks LL. *From a blame culture to a just culture in health care.* Health care management review. 2009;34(4):312-22.
11. Mearns K, Flin J. *Assessing the state of organizational safety - culture or climate?* Current Psychology. 1999;18(1):5-17.
12. Sexton JB, Helmreich RL, Neilands TB, Rowan K, Vella K, Boyden J, et al. *The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research.* BMC health services research. 2006;6:44.
13. Haerkens MH, van Leeuwen W, Sexton JB, Pickkers P, van der Hoeven JG. *Validation of the Dutch language version of the Safety Attitudes Questionnaire* (SAQ-NL). BMC health services research. 2016;16(a):385.

14. Paine LA, Rosenstein BJ, Sexton JB, Kent P, Holzmueller CG, Pronovost PJ. *Republished paper: assessing and improving safety culture throughout an academic medical centre: a prospective cohort study.* Postgrad Med J. 2011; 87(1028):428-35.
15. Howard SK, Gaba DM, Fish KJ, Yang G, Sarnquist FH. *Anesthesia crisis resource management training: teaching anesthesiologists to handle critical incidents.* Aviation, space, and environmental medicine. 1992;63(9):763-70.
16. Holzman RS, Cooper JB, Gaba DM, Philip JH, Small SD, Feinstein D. *Anesthesia crisis resource management: real-life simulation training in operating room crises.* Journal of clinical anesthesia. 1995;7(8):675-87.
17. Morey JC, Simon R, Jay GD, Wears RL, Salisbury M, Dukes KA, et al. *Error reduction and performance improvement in the emergency department through formal teamwork training: evaluation results of the MedTeams project.* Health Serv Res. 2002;37(6):1553-81.
18. Haller G, Garnerin P, Morales MA, Pfister R, Berner M, Irion O, et al. *Effect of crew resource management training in a multidisciplinary obstetrical setting.* International journal for quality in health care : journal of the International Society for Quality in Health Care / ISQua. 2008;20(4):254-63.
19. McCulloch P, Mishra A, Handa A, Dale T, Hirst G, Catchpole K. *The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre.* Qual Saf Health Care. 2009;18(2):109-15.
20. Hughes KM, Benenson RS, Krichten AE, Clancy KD, Ryan JP, Hammond C. *A crew resource management program tailored to trauma resuscitation improves team behavior and communication.* Journal of the American College of Surgeons. 2014;219(3):545-51.
21. Neily J, Mills PD, Young-Xu Y, Carney BT, West P, Berger DH, et al. *Association between implementation of a medical team training program and surgical mortality.* JAMA. 2010;304(15):1693-700.
22. Timmons S, Baxendale B, Buttery A, Miles G, Roe B, Browes S. *Implementing human factors in clinical practice.* Emerg Med J. 2015;32(5):368-72.
23. France DJ, Leming-Lee S, Jackson T, Feistritzer NR, Higgins MS. *An observational analysis of surgical team compliance with perioperative safety practices after crew resource management training.* American journal of surgery. 2008;195(4):546-53.

24. Salas E, Wilson KA, Burke CS, Wightman DC. *Does crew resource management training work? An update, an extension, and some critical needs.* Human factors. 2006;48(2):392-412.
25. Haerkens MH, Lorraine CJ, Oud CT, Pickkers P, Van der Hoeven JG. *Implementation challenges of Crew Resource Management.* ICU Management & Practice. 2016;16(2):90-1.
26. Hackman JR, Oldham GR. *Motivation through the design of work: Test of a theory.* Organizational Behavior and Human Performance. 1976;16(2):250-79.
27. Moreau E, Mageau G. *The importance of perceived autonomy support for the psychological health and work satisfaction of health professionals: Not only supervisors count, colleagues too!* Motivation and Emotion. 2012;36(3):268-86.
28. Credo KR, Armenakis AA, Feild HS, Young RL. *Organizational ethics, leader-member exchange, and organizational support: Relationships with workplace safety.* Journal of Leadership & Organizational Studies. 2010;17(4):325-34.
29. Rhoades L, Eisenberger R, Armeli S. *Affective commitment to the organization: the contribution of perceived organizational support.* The Journal of applied psychology. 2001;86(5):825-36.
30. Kao LS, Thomas EJ. *Navigating towards improved surgical safety using aviation-based strategies.* The Journal of surgical research. 2008;145(2):327-35.
31. Meterko M, Restuccia JD, Stolzmann K, Mohr D, Brennan C, Glasgow J, et al. *Response Rates, Nonresponse Bias, and Data Quality. Results from a National Survey of Senior Healthcare Leaders.* Public Opin Q. 2015;79(1):130-44.

Tables

Table 1

Demographic, Hospital, Department, and Position Frequencies per Measuring Moment.

Variable	Category[b]	Measure		
		Baseline	Post	Follow-up
		(*n* = 1412)	(*n* = 558)	(*n* = 270)
Gender	Male	443 (31.4%)	171(30.6%)	63 (23.3%)
	Female	939 (66.5%)	378(67.7%)	205 (75.9%)
Age[a]	≤ 20	25 (1.8%)	14 (2.5%)	-
	21-30	242 (17.1%)	95 (17.0 %)	32 (11.9%)
	31-40	373 (26.4%)	134 (24.0%)	78 (28.9%)
	41-50	404 (28.6%)	164 (29.4%)	70 (25.9%)
	> 50	352 (24.9%)	174 (26.3%)	89 (33.0%)
Hospital	Academic (3/2/1)	451 (31.9%)	244 (43.7%)	220 (81.5%)
	Teaching (7/7/1)	961 (68.1%)	314 (56.3%)	50 (18.5%)
Department[c]	MCU (1/1/0)	27 (1.9%)	6 (1.1%)	-
	ICU (2/2/1)	270 (19.1%)	179 (32.1%)	220 (81.5%)
	OR (5/5/0)	583 (41.3%)	233 (41.8%)	-
	CCL (3/2/0)	167 (11.8%)	45 (8.1%)	-
	ER (2/2/1)	138 (9.8%)	74 (13.3%)	50 (18.5%)
	CCU-HFA (2/1/0)	77 (5.5%)	21(3.8%)	-
	RTX (1/0/0)	11 (0.8%)	-	-
	DGH (1/0/0)	36 (2.5%)	-	-
	Pharmacy (1/0/0)	34 (2.4%)	-	-
	Obstetrics (1/0/0)	69 (4.9%)		
Position	Nurse[d]	743 (52.6%)	355 (63.6%)	228 (84.4%)
	Resident	101 (7.2%)	45 (8.1%)	5 (1.9%)
	Att. physician[e]	256 (18.1%)	106 (19.0%)	22 (8.1%)

Note. [a] Age categories in years; [b] Between parentheses are numbers per (pre/post/follow-up) measure; [c] MCU = Medium Care Unit, ICU = Intensive Care Unit, OR = Operating Room, CCL = Cardiac Catheterization Lab, ER = Emergency Room, CCU-HFA = Coronory Care Unit – Heart First Aid unit, RTX = Radiotherapy, DGH = Department of Gastroenterology and Hepatology; [d] Nurse category consists of nurses, operating room technicians, and anesthesiology technicians; [e] Att. physician = Attending physician.

Table 2

Means, Standard Deviations, Contrasts, and Effect Size for Safety Climate Domains per Measuring Moment

Domain	Measuring Moment						
	Baseline	Post			Follow-up		
	M (*SD*)	*M* (*SD*)	p^1	d^1	*M* (*SD*)	p^2	d^2
Teamwork	65.0 (14.2)	67.7	<	.1	74.53	<	.51
Climate		(13.9)	.001	9	(13.5)	.001	
Safety Climate	61.5 (14.2)	63.6	<	.1	71.0	<	.57
		(13.8)	.002	5	(12.4)	.001	
Job	65.0 (16.4)	64.8	.87	.0	74.4	<	.64
Satisfaction		(16.2)		08	(13.5)	.001	
Stress	49.2 (17.9)	52.7	.001	.2	54.9	.036	.12
Recognition		(17.5)		0	(19.3)		
Perceptions of	48.0 (14.9)	53.4	<	.3	55.9	.082	.17
Management		(16.3)	.001	6	(14.1)		
Working	56.2 (15.9)	56.1	.98	.0	64.9	<	.58
Conditions		(16.0)		01	(14.0)	.001	

Note. Pre n = 1412, Post n = 558, Follow-up n = 270; d = Cohen's d, calculated with pooled standard deviation; [1] Pre vs. Post; [2] Post vs. Follow-up.

Table 3
Overview of Most Cited Points for Improvement

Subject	Category	Example	Frequency
Situational Awareness	Briefing / debriefing	Discuss the days operations program with the entire team before starting the day and adress particularities.	78 (83%)
	Handover	More structured handover of patients. Too much information does not get transferred.	29 (31%)
	Equipment	Standardization of monitor colors, e.g. saturation always blue.	11 (12%)
Communication	Assertiveness in escalation	Implement 3 levels of escalation in potentially unsafe situations; 1. I [think, see, etc.], 2. I'm not comfortable, 3. Stop this procedure.	60 (64%)
	Names	Make sure we know everybody by name during a procedure.	33 (35%)
	Noise reduction	Procedure room needs to be more quiet. There is too much talking and there are often too many people in a limited space.	32 (34%)
	Closed-loop	Confirm medication with an open-ended question; "what is this?"	25 (27%)
	Address behavior	Address wanted and unwanted behavior and give proper performance feedback.	15 (16%)
Stress	Aftercare	Debriefing of traumatic experiences with the other team members.	22 (23%)
	Recognition	Address personal limitations in the team; is everybody 'fit to fly'?	15 (16%)
Group Processes	Conflict	More talking with each other and less about each other; don't let irritation become conflict.	16 (17%)
	SOP	Describe fixed roles, tasks, and responsibilities when receiving a trauma patient.	12 (13%)
Leadership	Unambiguous	Speak out on who is in charge in critical situations.	35 (37%)
Human Error	Safe reporting	Create a compartment in which we can learn from others' mistakes and near-misses.	35 (37%)

Note. *N* = 94 lists; Only categories that appeared in 10 or more of the lists with points for improvement are displayed; SOP = Standard Operating Procedures.

Figures

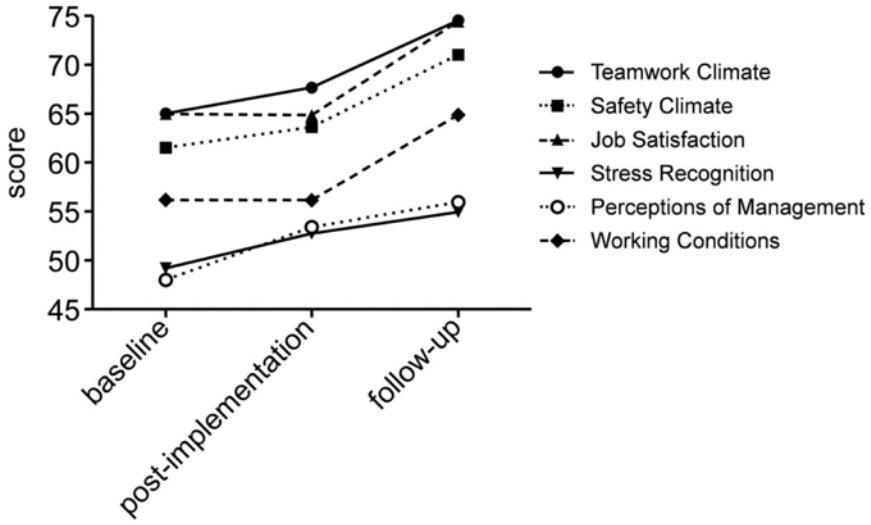


Figure 1

Development of safety climate domains over two years.

Mean values are depicted. Note that a limited section of the scale is displayed to prevent cluttering of lines.

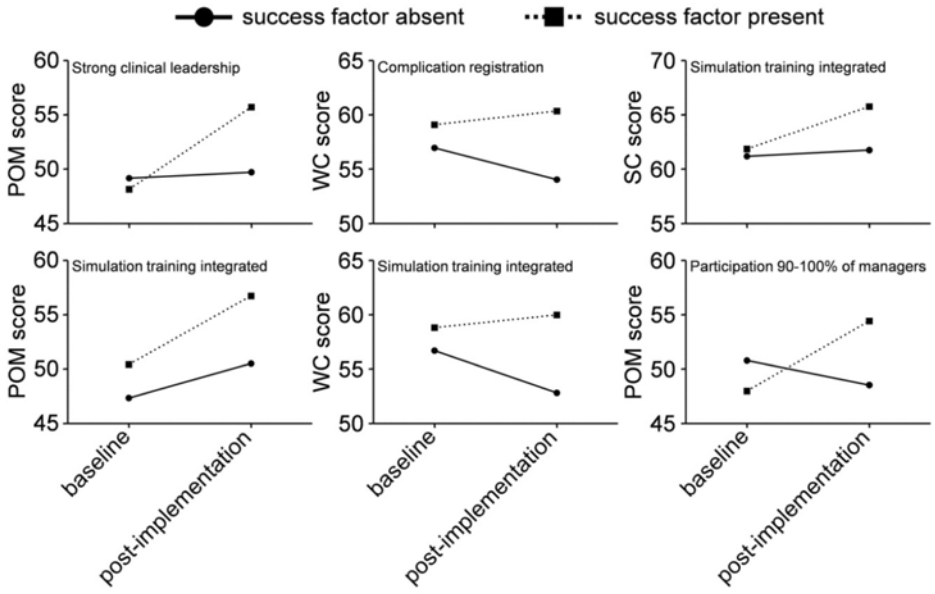


Figure 2

Moderating effects of success factors on safety climate domains.

Success factors are indicates in the graphs. Mean values are depicted on the y-axis. Note that a limited section of the scale is displayed to prevent cluttering of lines. POM = Perceptions of Management; WC = Working Conditions; SC = Safety Climate.

6.2
Implementation challenges

Based on:

Implementation Challenges of Crew Resource Management
MHTM Haerkens
CJ Lorraine
TC Oud
P Pickkers
JG van der Hoeven

J ICU Management & Practice 2016; 16(2):88, 90-91

Never waste an opportunity to debrief (invited review)
J Lemson
MHTM Haerkens

Critical Care Medicine 2014; 42:7, 1740-1741

Summary

CRM Human Factors awareness training is a useable tool to improve patient safety in clinical medicine and may fill a void in medical education curricula. However, changing traditional ways of working and improving professional interaction remains a challenging task.

Hands-on experience with CRM in more than 19 high-risk clinical departments has yielded insight into the factors impacting CRM implementation into the clinical environment.

While introducing CRM as a clinically-led, non-facultative and safe (confidential) multidisciplinary teamwork format may lead to improved safety climate and clinical performance in a department, we find that these effects will only be sustainable if actively supported by the hospital administration. Ultimately, a national CRM-training and evaluation standard is considered essential.

Introduction

Performing high risk, time critical procedures, including CPR, is challenging. Although mortality may be high, the majority of survivors show a favorable neurological outcome1. Importantly, clinical outcome following cardiac arrest is not only determined by the technical and procedural proficiency of the CPR code team and department logistics[2,3], but also by the non-technical performance of the professionals involved. This includes team-related dynamics, as discussed in chapter 1 of this thesis. Optimal leadership and followership behavior will strongly influence CPR team results. Furthermore, adequate and timely performance feedback during the procedure may help avoid mistakes. Also, structured performance feedback after procedures (debriefing) may identify lessons to be learned and enhance future team performance and outcome.[4,5,6]

The Human Factor (HF) awareness concept entitled Crew Resource Management (CRM) focuses on teamwork, threat and error management, and blame-free discussion of human mistakes. This concept originated in the aviation domain, but has clear potential for the clinical environment, especially in high-risk departments.[7,8]

In aviation, CRM is a multidisciplinary non-technical skills standard for aircrew. Any CRM-training has to meet Federal Aviation Authority (FAA) or European Aviation Safety Agency (EASA) regulations.[9,10] Not only do these regulations define the various subjects and the extent to which each subject should be discussed, but they also set limits for training duration, refresher training frequency and trainer requirements.

Evidence is increasing that CRM is also a promising tool for culture change in high-risk clinical departments. Unfortunately, currently, standardization in medical HF-training initiatives is lacking. As a consequence, large variations in curriculum, duration, intensity, feed-back and follow-up support exist.

Our approach

To reach a credible national standard for CRM in medical training and operations an evidence-based curriculum is key.[11] Our research includes data from CRM "culture-interventions" in more than 19 high-risk clinical departments in university and training hospitals, and investigates the impact on safety climate and clinical performance.
Clearly, implementing CRM in departments whose professionals have had no previous formal HF education requires more than just training. Therefore, we introduced a three–phase "intervention" approach, consisting of a preparation, training, and implementation phase, including feedback of results.

The three-month preparation phase kicks off with a plenary session to inform all training participants on the upcoming CRM-training and implementation flow. Even though CRM relies on intrinsic motivation to be effective, we encourage the department leadership to clarify to all staff in advance that CRM will become the non-facultative professional standard, serving as a yardstick for professional evaluation.
Subsequently, the department's safety climate is assessed using the SAQ-NL (as described in chapter 2), onsite process observations are conducted by CRM-trainers and video-footage of critical communication moments is gathered.

The training phase's multidisciplinary sessions are performed within a three-month window to maximize impact and held at a facility at some distance from the hospital to minimize interference. The maximum amount of participants for training sessions is 15. Sessions are conducted by two trainers with a credible operational and scientific background.
The well-developed two-day standard course includes lectures on HF and principles of CRM, multiple interactive sessions using realistic data (such as case studies), and video footage from the trained department.

The training emphasizes nine key areas: situational awareness and recognition of adverse situations; human errors and non-punitive response; communication and briefing and debriefing techniques; providing and receiving performance feedback, management of stress; workload and fatigue; creating and maintaining team structure and climate; leadership; risk management; and decision-making.[11]
Each training group is challenged to produce a shortlist of practical "action points" to be converted into practical clinical tools in the following implementation phase.

The one-year implementation phase aims to integrate and develop the CRM way of professional interaction within the department. The intended culture change is supported by additional implementation measures like the formation of a CRM "core group" and scenario-based team training sessions.
The core group, consisting of volunteer clinical professionals, is tasked with the coordination of the efforts to convert the CRM action points into clinical practice.11 They receive additional coaching during the implementation year. Clearly, it is important for the clinical leadership to empower the core group activities, thereby creating joint "ownership".
Scenario-based team training, also called simulation, is encouraged as a follow-up measure to reinforce the effect of CRM-based culture change. Scenario-based team training creates a zero-risk environment that allows medical teams to practice high-risk, low-frequency events without endangering patients. Simulation can be done in an artificial "laboratory" environment or as *"in situ"* training, which is conducted on actual patient care units, involving actual health care team members and actual organization processes.[11] If well debriefed, simulation has many advantages, but if used as a stand-alone measure without the basis of CRM-training there is a risk of focusing too much on individual technical skills and single-task performance. This could result in a limited impact on overall safety.

The basis for scenario-based team training in healthcare is the identification of the domain-specific team skills required to manage routine and emergency scenarios. Based on aviation simulation experience we suggest using two separate phases of simulation training: the first level of training mainly focuses on technical and procedural skills. Only after having completed CRM-training, participants may be scheduled for second level simulation training, which emphasizes nontechnical (team)performance.

Defining and measuring success

As the ultimate goal of Crew Resource Management is to improve patient safety, defining elements of CRM success could be: acceptance by the professionals and management, improved safety climate, and ultimately to a decrease in complications and improved patient outcome.

However, objective determination of these factors has proved challenging. We encountered the following limitations:

- Training evaluation scores could be considered as indicators of acceptance by participating professionals and managers, but only indirectly so.
- Safety climate was measured in all projects with the Safety Attitudes Questionnaire (SAQ-NL, see chapter two), but response rates varied extensively.
- Reliable determinations of complications proved challenging in 17 out of 19 clinical departments, as registration is performed by specialisms independently of each other, and data are rarely traceable to a specific department (e.g. the Emergency Department or Operating Room). The only departments that supplied us with solid complication data were the ICU's, participating in the Dutch National Intensive Care Evaluation (NICE) that records a predefined set of complications.[12]

Experience with CRM-implementation

Our experience with CRM-implementation in 19 high-risk clinical departments in the Netherlands is encouraging: First, the training evaluation scores were high in all trained departments. We consider this an indication

that the aviation-derived training concept was highly appreciated by medical professionals and identified as an important part of professional self-regulation. Second, as discussed in chapter 6.1, CRM was associated with a positive effect on all domains of perceived safety climate. Third, as discussed in Chapter 4 of this thesis, we found CRM-implementation in the ICU was associated with a reduction in serious complications and lower mortality in critically ill patients (next to an improved safety climate).[12] Due to the aforementioned lack of registration of complication in other departments, reliable reproduction of these data in other settings was not feasible. Still, also important barriers to implementation[13] were encountered on a financial, organizational, managerial and professional level. Ever increasing financial and time constraints challenge the funding and time investment crucial for CRM training and implementation efforts. Although one of our projects was awarded the 2013 Dutch Health Inspectorate's national Patient Safety Award, to date Dutch national medical societies and health insurers have not yet agreed on funding for a national Human Factors training curriculum for healthcare professionals.

In our experience, traditional hospital organizational structures and existing department cultures may induce a general reluctance to change ways of working, especially if they are thought to involve additional effort. The required leadership by example from senior staff members unfortunately proved to be more exception than rule. Furthermore, integrating managers/administrators into the CRM-implementation process proved challenging as expectations toward management's role varied. CRM trainees expected management to facilitate CRM implementation by allowing sufficient time and adequate funding, but frequently underestimated the requirement for active support from and cooperation with managers, both local and corporate.

While clinicians were in general enthusiastic about initiating and leading CRM activities, they often became more ambivalent if it led them into more 'managerial' activity. This deep-seated concern about managerial work remains an obstacle to the development of HF in healthcare. Our approach to introduce CRM as an initiative led by clinicians requiring a disengaged

but supportive stance of the hospitals' management probably improved the acceptation by the professionals, but this bottom-up approach may, in some cases, have caused managers to adopt a negative – "not invented here" – attitude and disengage from the implementation process, and thus weakening the initiative.

Hands-on experience from the aforementioned 19 CRM implementation projects, as well as the results from the longitudinal study described in chapter 6.1, helped us identify some key success factors as well as threats to success that may be of use to future clinical CRM initiatives. Table 1 contains an overview of empiric success factors and threats to success.

Conclusions

Aviation-based CRM Human Factors awareness training is a useful tool in clinical medicine that increases perceived safety climate and has the potential to improve clinical outcome. However, adapting the organizational context to fully integrate the Human Factors principles into daily operations remains challenging. Nevertheless, with the identification of success factors as well as threats to success, successful implementation is possible. Currently, an (inter)national standard for medical CRM-training and evaluation is lacking. For CRM to truly impact safety for all patients, it should be an obligatory component of healthcare. Therefore, a national standard should be agreed upon, from under-graduate curricula to daily clinical operations. This standard will facilitate compatibility, safety and quality in multidisciplinary care.

Furthermore, it will make it easier to compare educational service providers.

References

1. López-Herce J, Del Castillo J, Matamoros M, Cañadas S, Rodriguez-Calvo A, Cecchetti C, et al: *Factors associated with mortality in pediatric in-hospital cardiac arrest: a prospective multicenter multinational observational study.* Intensive Care Med 2013; 39:309-318
2. Wallace SK, Abella BS, Becker LB: *Quantifying the effect of cardiopulmonary resuscitation quality on cardiac arrest outcome: a systematic review and meta-analysis.* Circ Cardiovasc Qual Outcomes 2013; 6:148-156
3. Gaies MG, Clarke NS, Donohue JE, Gurney JG, Charpie JR, Hirsch JC: *Personnel and unit factors impacting outcome after cardiac arrest in a dedicated pediatric cardiac intensive care unit.* Pediatr Crit Care Med 2012; 13:583-588
4. Wolfe H: *Interdisciplinary Intensive Care Unit Cardiac Arrest Debriefing Improves Survival Outcome.* Crit Care Med 2014;
5. Sutton RM, Nadkarni V, Abella BS: *"Putting it all together" to improve resuscitation quality.* Emerg Med Clin North Am 2012; 30:105-122
6. Couper K, Salman B, Soar J, Finn J, Perkins GD: *Debriefing to improve outcomes from critical illness: a systematic review and meta-analysis.* Intensive Care Med 2013; 39:1513-1523
7. Eisen LA, Savel RH: *What went right: lessons for the intensivist from the crew of US Airways Flight 1549.* Chest 2009; 136:910-917
8. Ornato JP, Peberdy MA: *Applying lessons from commercial aviation safety and operations to resuscitation.* Resuscitation 2013;
9. EASA publication AMC1.1 ORO.FC.115&215 *Crew resource management (CRM) training*
10. FAA Part 121: *Operating Requirements: Domestic, Flag, and Supplemental Operations,* article §121.404 Compliance dates: Crew and dispatcher resource management training.
11. Haerkens MHTM, Jenkins DH, van der Hoeven JG. *Crew resource management in the ICU: the need for culture change.* Ann Intensive Care 2012;2:39.
12. Haerkens MHTM, Kox M, Lemson J, Houterman S, van der Hoeven JG, Pickkers P. *Crew Resource Management in the Intensive Care Unit: a prospective 3-year cohort study.* Acta Anaesthesiol Scand 2015;59:1319–1329
13. Timmons S, Baxendale B, Buttery A, Miles G, Roe B, Browes S. *Implementing human factors in clinical practice.* Emerg Med J 2015;32:368–372.

Tables

Table 1: Success factors and threats to success

Success factors	**background**
The initiative is clinically-led	Helps convince other clinicians of the relevance of HF awareness in daily practice.
Training is delivered largely by clinicians	Facilitates acceptance of the curriculum and case discussions.
Confidentiality is maintained throughout the intervention	Essential for discussions on sensitive subjects, such as case discussions.
Participation is non-facultative for all staff members, students and operational managers	Helps all professionals involved in the care process to recognize and appreciate changes resulting from the CRM training.
Training is conducted in multi-disciplinary groups	Increases understanding of each other's problems and limitations whilst making it impossible to apportion blame to groups not represented in the training.
Hospital administrator is involved	Helps position CRM as multidisciplinary clinical standard, and "make things happen"
Hospital managers take a supportive, but "hands-off" stance	Facilitates organizational change, and helps clinical professionals appreciate the importance of managerial support.

Threats to success	**background**
Poorly managed expectations of the project	May result in the idea that CRM training in and of itself will yield a culture change, and lead to underestimation of the required implementation efforts.
Lack of a solid implementation plan and realistic timeline	Improvement is unlikely to be seen within one year and requires dedication and tenacity from all involved[11,13]
Delay in initiating timely and noticeable improvements in daily practice	Makes it harder for professionals to relate the improvements to the CRM initiative.
Insufficient accountable operational leadership	If clinical leaders do not set the example, safety climate change will not be possible.
Disengagement of hospital administrator and management	Will frustrate bottom-up initiatives from the work floor.
CRM is used as "window dressing"	May result in inadequate follow-up and very limited commitment of caregivers.

7.1
Summary

Summary

Despite modern equipment, increasing emphasis on patient safety, and excellent training facilities, medical care frequently results in unintentional harm to patients. Reliable studies on medical error are scarce, as they need to rely on data extractable from documented inpatient health records, which makes identifying the key factors in safe care a challenging task. Human Factors (HF) appear to play an important role in adverse events, especially in departments where high risk, time critical procedures on vulnerable patients are performed in a multidisciplinary team setting.
As perceived safety climate is positively related to safety outcomes both in hospital settings and other high-hazard fields, a sound safety climate is considered essential.

This thesis has focused on HF and critical team performance in clinical medicine. We validated an open source safety climate assessment tool (the SAQ-NL) and developed an aviation-derived team concept for the clinical setting (Crew Resource Management - CRM), including a training syllabus and implementation plan. In addition, we performed the CRM safety climate intervention in multiple hospital departments. and assessed its impact on patient safety.

Chapter one provided an introduction into the educational and operational safety issues of the clinical healthcare system in the Netherlands as well as an outline of the thesis.

In **chapter two** safety climate in a variety of clinical departments in Dutch hospitals was investigated and yielded a validated open-source instrument to measure safety climate in the Dutch clinical setting, the Safety Attitudes Questionnaire-NL (SAQ-NL). As removal of one item resulted in an increased reliability of the Working Conditions dimension, revision or deletion of this item should be considered. The results from this study

provide researchers and practitioners with insight into safety climate in a variety of departments and functional positions in Dutch hospitals.

In **chapter three** the existing literature on CRM and its application in critical care medicine was reviewed. Furthermore, both the framework of our HF awareness training curriculum specifically aimed at care teams, as well as a three-phase structure for the CRM safety climate intervention was described. Even though evidence of the impact of CRM on medical errors and patient outcome is still scarce, the parallels between the critical processes in aviation and Intensive Care (ICU) suggest that a well-adapted medical CRM training has potential for the ICU environment.

Chapter four described a study into the impact of a CRM-intervention in a large ICU on patient outcome. The CRM-implementation was associated with a reduction in serious complications and lower mortality in critically ill patients. These clinically relevant effects paralleled a positive impact on the perceived safety climate by the health care providers.

In **chapter five**, the effects of a CRM-intervention in the Trauma Room setting of a level 1 Emergency Department was described. Although CRM-implementation in the ED was associated with an improved safety climate, the time spent by trauma patients in the ED increased.

In **chapter six**, the impact of CRM implementation on safety climate in 17 high-risk clinical departments was investigated, and this impact was related to perceived implementation success factors as well as threats to success.
It was found that CRM implementation is associated with an improved safety climate. Also a shortlist of factors associated with successful CRM implementation, as well as factors associated with failure of implementation, was provided. Furthermore, points for improvement that healthcare professionals wanted to implement after receiving CRM training, and possible existing barriers to transfer of the CRM training to the work floor, were identified.

Chapter seven summarized all research findings and discussed current issues and future perspectives for CRM. Although aviation-based CRM/ Human Factors awareness training may prove a useful tool in medicine, adapting the medical organizational context to fully integrate the Human Factors principles into daily health operations remains a challenge. Operational, educational and inspectorate/judicial aspects of this challenge are discussed.

It is concluded that only after an national medical CRM-training and operational standard is agreed upon, the CRM Human Factors awareness program may mature into an effective component of under- and post-graduate (para)medical curricula.

7.2
Future perspectives

Based on:

Team aspects of Patient Safety
MHTM Haerkens
Dutch Patient Safety Manual 2016; Part 5, Chapter 23.
ISBN: 9789058983060

Crew Resource Management
ECTH Tan
MHTM Haerkens
Acute Healthcare 2014; Chapter 1.4. ISBN: 9789035236233

Future perspectives

Despite modern equipment, permanent education, continuing research and excellent training facilities medical care frequently results in unintentional harm to patients. Medical error is currently estimated to be the third leading cause of death in the United States, with over 250,000 patients having died as a result of preventable adverse events in 2013.[1] The actual numbers may even be higher, for underreporting is likely as standardized root cause analysis, reporting of inpatient deaths and national data sharing is limited.[1] Although some medical errors can be attributed to technical malfunctions and failing equipment, many find their roots in the area of Human Factors (HF). It may therefore be reasonable for the healthcare community to improve HF awareness and non-technical skills in order to reduce medical error and increase safety.

Safety Climate

Each healthcare professional carries the responsibility to operate competently, safely and in the best interest of the patient. However, as safe care relies on the interdisciplinary performance of a care team as much as on individual expertise, a "just" safety culture may prove a sound basis for better patient outcomes.[2] As described in chapters two and three of this thesis, safety climate is positively related to safety outcomes (both in hospital settings and other high-hazard fields), responsive to interventions, and can be reliably determined through surveys. Therefore it may be valuable for all high-risk clinical departments to gauge their safety climate on a regular basis.

Future of CRM

There are critical needs to be met for CRM to have a role in national patient safety: additional convincing research, a clear mandate and sufficient resources.[3]

The first most obvious need is the access to more convincing high-quality research. Despite encouraging results from local healthcare CRM-interventions, there is a lack of studies establishing a credible, direct cause-and-effect relationship between CRM training and safety. These studies should include all levels of Kirkpatrick's evaluation framework with an accent on observed explicit professional behavior and patient outcomes, data that may not be readily available for multiple reasons (see below).

A clear mandate - on multiple levels - is a second necessity, as professional safety attitudes are forged during training and influenced by daily practice and even legal context. Therefore, it would make sense to allow a national organization of healthcare professionals, such as the Dutch Federation of Medical Specialists (Federatie Medisch Specialisten - FMS), the mandate to focus future efforts to improve safety climate on operational patient care, educational system as well as inspectorate/judicial level.

1. On an operational level several non-technical issues have an impact on care team performance. First, leadership/followership roles in health care teams should be re-defined, focusing on team role and situational competence, not traditional hierarchic position. Traditional hierarchy negatively influences cooperation within care teams (eg. doctors vs. nurses, junior vs. senior staff), between different clinical specialties, and is also noticeable in the relationship between hospital administrators and medical professionals. For this to improve, leadership and followership skills should be considered core competences for medical professionals. CRM may serve as a common basis for this skill set. Second, as discussed in chapter 6, structured debriefing should become a predictable, non-facultative part of every critical operational process. Debriefing is a powerful tool to identify lessons to be learned shortly after a procedure, with the sole purpose to improve future individual and team performance and prevent an incident or near-miss from ever occurring again. Third, failure to share errors and adverse events with colleagues remains an important problem in care, as other team members can only learn from errors that have been disclosed.[4]

Differences between doctors and nurses in the willingness to report unintended events exist.[5] Additionally, patients and caregivers may have different ideas about what constitutes a medical error or adverse event[4] or which information needs to be shared with whom. To achieve the aforementioned "just culture" national healthcare organizations should agree upon a national multidisciplinary standard in medical team dynamics. This may require changes to the educational system and the inspectorate/judicial context.

2. The medial educational system is traditionally more focused on individual craftsmanship and professional autonomy than on non-technical skills such as leader- (and follower-) ship, team dynamics and communication. To date, many university and training hospitals have no comprehensive HF awareness curriculum and lack sufficient HF expertise. This often results in outsourcing of training. Following encouraging reports on the effects of HF-awareness training in clinical medicine many commercial CRM-derived training initiatives arose - without any standard for trainers, training content and duration, or implementation approach.

For this to change, Dutch healthcare organizations and authorities should first aim to achieve consensus on a robust standard for HF awareness teaching and skill evaluation for (para)medical professionals. Second, recognizing the traditional barriers that exist between doctor's and nurse's training institutes, it should strive towards a truly multidisciplinary under- and postgraduate HF awareness training curriculum. As mentioned earlier, a robust national organization of healthcare professionals (like the FMS) should be mandated to coordinate these efforts.

3. Finally, on an inspectorate/judicial level there are challenges that need to be addressed: in contrast to the aviation domain, the Dutch medical incident reporting system has currently no well-defined "blame-free" legal compartment with the sole purpose to enable all professionals to learn from errors that have occurred. As a consequence, every safety report may end up directing undesired attention from healthcare and judicial authorities towards the medical professional. This does not facilitate low-threshold safety reporting, despite current efforts to establish incident reporting and

learning systems in healthcare.[5] As previously discussed, authorities should consider initiating a non-blaming incident report database, with oversight separated from both the Health Inspectorate and legal system. Beyond the scope of this thesis, but a potential factor nonetheless, is the recent development that Dutch personal injury lawyers are allowed to adopt the no cure no pay – fee system for law suits during a 5-year experimental period
ending January 1, 2019.[6] If this revenue model were to become permanent, the perception that it may encourage an increased motivation for law suits (and the concurrent fear of "ambulance chasers") would not help in lowering the disclosure threshold for healthcare professionals.

An effective national CRM initiative also requires sufficient financial and human resources, as CRM research, development and implementation is very labor intensive.
First, resources are needed to standardize training evaluation and to properly train sufficient trainers and evaluators. Additionally, if CRM efforts were to continue as local hospital initiatives with early adapters, outsourcing training to commercial organizations would remain too costly. Adequate, centralized funding would facilitate a coordinated development of training content, integration into existing undergraduate curricula as well as continuous medical education.[7] Finally, establishing the cost effectiveness of CRM in healthcare is a very challenging endeavour, as both CRM training and implementation strategies and calculation methods differ. A representative overview of medical errors as a cause for patient harm (and their costs) is usually not available.
The few studies aiming to establish the cost effectiveness of CRM in healthcare show variable results. Moffatt-Bruce et al conclude that CRM presents a financially viable way to systematically organize quality improvement,[8] while Kemper et al found that their CRM implementation was not cost effective because they were unable to show a beneficial effect on patient outcome.[9]

Meanwhile, the devastating loss of human life and colossal cost (in the US alone estimated at $1 trillion each year[10]) resulting from preventable medical error may warrant continuation of HF awareness investments.

Future research

This thesis may serve as a basis for future research to further enhance the SAQ-NL safety climate questionnaire or CRM training content. Furthermore, additional longitudinal studies are needed to ascertain the impact of CRM on patient outcome in different clinical settings, and to identify when the effects of CRM decline to provide information on when refresher training is appropriate. To evaluate cost effectiveness we would encourage future studies with larger study populations and longer follow-up.

The Crew Resource Management Human Factors awareness program may mature into an effective component of under- and postgraduate (para)-medical curricula. But only after an (inter)national medical CRM-training and operational standard is agreed upon.

It is time that we should appreciate the human factor.

References

1. Makary MA, Daniel M. *Medical error - the third leading cause of death in the US.* BMJ 2016; 353:i2139
2. Paine LA, Rosenstein BJ, Sexton JB, et al. *Assessing and improving safety culture throughout an academic medical centre: A prospective cohort study.* Postgrad Med J 2011; 87:428–435
3. Salas E, Wilson KA, Burke CS, Wightman DC. *Does Crew Resource Management Training Work? An Update, an Extension, and Some Critical Needs.* Human Factors 2006; 48(2):392–412
4. Boyle D, O'Connell D, Platt FW, Albert RK. *Disclosing errors and adverse events in the intensive care unit.* Crit Care Med 2006; 34:1532–1537
5. Wagner C, Merten H, Zwaan L, et al. *Unit-based incident reporting and root cause analysis: variation at three hospital unit types.* BMJ Open 2016; 6:e011277.
6. Verordening op de advokatuur, Afdeling 7.4, Paragraaf 7.4.3 *Experiment letsel- en overlijdensschadezaken. Nederlandse Orde van Advokaten.* Website http://regelgeving.advocatenorde.nl/content/afdeling-74-resultaatgerelateerd-honorarium
7. Salas E, Wilson KA, Burke CS, Wightman DC. *Does Crew Resource Management Training Work? An Update, an Extension, and Some Critical Needs.* Human Factors 2006; 48(2):392–412
8. Moffatt-Bruce SD, Hefner JL, Mekhjian H, et al. *What Is the Return on Investment for Implementation of a Crew Resource Management Program at an Academic Medical Center?* Am J Med Qual 2015; pii: 1062860615608938
9. Kemper PF, de Bruijne M, van Dyck C, et al. *Crew resource management training in the intensive care unit. A multisite controlled before–after study.* BMJ Qual Saf 2016; 0:1–11
10. Andel C, Davidow SL, Hollander M, Moreno DA. *The economics of health care quality and medical errors.* J Health Care Finance 2012; 39(1):39-50

8.
Appendices

8.1
Summary in Dutch - Samenvatting

Samenvatting

Ondanks moderne apparatuur, evidence based standaarden, veiligheids-instrumenten, kwaliteitsindicatoren, veiligheidsmanagementsystemen, certificeringen en audits resulteert medische zorg nog te vaak in onbedoelde schade voor de patiënt.
Betrouwbare studies over medische fouten zijn schaars, en maken gebruik van data afkomstig uit medische statussen. Dit maakt het identificeren van leermomenten een uitdagende taak. Human Factors (HF) spelen een belangrijke rol in incidenten in alle hoog-risico processen. Binnen de zorg gaat het dan speciaal om afdelingen waar risicovolle, tijdskritische procedures worden verricht door multidisciplinaire teams op kwetsbare patiënten.
Een optimaal veiligheidsklimaat is belangrijk, aangezien het positief correleert met procesveiligheid, zowel in de medische zorg als andere hoogkritische sectoren.

Dit proefschrift is gericht op het verband tussen HF en het functioneren van hoogkritische teams binnen de klinische patiëntenzorg.
Een instrument ter meting van het veiligheidsklimaat werd gevalideerd (SAQ-NL), en een uit de luchtvaart afkomstig teamtrainingsconcept werd toegesneden op de ziekenhuisomgeving (Crew Resource Management - CRM), inclusief een training syllabus en implementatieplan. De CRM-cultuurinterventie werd vervolgens toegepast in meerdere ziekenhuis-afdelingen, en de invloed op patiëntveiligheid werd onderzocht.

Hoofdstuk 1 geeft een introductie in de uitdagingen rondom patiënt-veiligheid op opleidings- en operationeel gebied, en biedt tevens een overzicht van het proefschrift.

In **hoofdstuk 2** werd het veiligheidsklimaat onderzocht op verschillende ziekenhuisafdelingen met een aan de Nederlandse taal en context aan-gepaste wereldwijd gebenchmarkte vragenlijst (Safety Attitudes

Questionnaire - SAQ) teneinde tot een gevalideerd, en voor eenieder beschikbaar, meetinstrument te komen voor veiligheidsklimaat in de Nederlandse klinische setting (SAQ-NL). De SAQ-NL liet prima eigenschappen zien. Wel is aanpassing of verwijdering van 1 vraag te overwegen, aangezien dat de betrouwbaarheid van de Arbeidsomstandigheden-dimensie zou vergroten. De resultaten van deze studie bieden zowel onderzoekers als medische professionals inzicht in het veiligheidsklimaat voor een variëteit aan afdelingen en beroepsgroepen binnen ziekenhuizen.

In **hoofdstuk drie** werd de beschikbare literatuur over HF en CRM en de toepassing binnen hoogkritische medische zorgprocessen besproken. Bovendien werd ons CRM opleidingscurriculum voor niet-technische vaardigheden en teamfunctioneren in de zorg beschreven, evenals onze drie-fasische aanpak voor de CRM veiligheidsklimaat-interventie. Alhoewel het beschikbare wetenschappelijke bewijs voor het effect van CRM op patiëntenzorg nog zeer beperkt is, duiden de parallellen tussen de hoogkritische processen binnen zorg en luchtvaart op het mogelijke nut van een goed op de (intensieve) zorg toegesneden medische CRM variant.

Hoofdstuk vier beschreef een studie naar de invloed van een CRM-interventie op de patiëntenzorg. De CRM-implementatie was geassocieerd met een afname van ernstige complicaties en verminderde sterfte bij ernstig zieke patiënten. Deze klinisch relevante effecten gingen gepaard met een verbetering van het veiligheidsklimaat op de afdeling.

In **hoofdstuk vijf**, werden de effecten van een CRM-interventie op de traumakamer van een level 1 Spoedeisende Hulp (SEH) onderzocht. Alhoewel de introductie van CRM op de SEH geassocieerd was met een verbeterd veiligheidsklimaat, nam de verblijfsduur van traumapatiënten op de SEH toe.

In **hoofdstuk zes** werd de invloed van CRM op het veiligheidsklimaat van 17 hoogrisico klinische afdelingen onderzocht, waarbij deze invloed werd

gecorreleerd met empirische succes- en faalfactoren voor implementatie. De resultaten lieten zien dat CRM implementatie geassocieerd is met een verbeterd veiligheidsklimaat, en resulteerden tevens in een korte lijst van succes- en faalfactoren voor CRM implementatie. Bovendien werden verbeterpunten geformuleerd door zorgprofessionals tijdens alle CRM-trainingen (actiepunten) geïnventariseerd, evenals barrières voor het doorvoeren van geleerde methodieken (en actiepunten) op de werkvloer.

Hoofdstuk zeven bevatte een samenvatting van alle onderzoeksresultaten en besprak huidige situatie en toekomstige perspectieven voor het CRM initiatief. Alhoewel een goed op de zorg toegesneden CRM concept veelbelovend is, blijkt het zodanig aanpassen van een ziekenhuisorganisatie dat de HF-principes volledig worden geïntegreerd in de dagelijkse patiëntenzorg momenteel nog uitdagend. Zowel de operationele, opleidings, inspectie, als juridische aspecten van deze uitdaging werden besproken.

Er werd geconcludeerd dat Crew Resource Management kan rijpen tot een waardevolle component van multidisciplinaire medische zorg en alle (para)medische opleidingen, op voorwaarde dat we in staat zijn om tot een nationale standaard te komen. Dit proefschrift beoogt daarvoor een basis te bieden.

8.2
Publications

International

de Boer HD, Haerkens MHTM, van der Stappen SW, van Ingen G, Wobbes T:
Testicular Carcinoma: postmortem diagnosis of testicular cancer.
Lancet 2002; 359: 1666.

Vaneker M, van Egeraat SPM, Haerkens MHTM, Wilder-Smith OH:
Letter to the editor in response to the article of Dekkers and Søballe (Activities and impairments in the early stage of rehabilitation after Colles' fracture; Vol. 26, No. 11, June 3, 2004)
Disabil Rehabil 2005; 27(9):535-6

Haerkens MHTM, Jenkins DH, van der Hoeven JG:
Crew resource management in the ICU: the need for culture change
Ann Int Care 2012; 2:39

Haerkens MHTM, Kox M, Lemson J, Houterman S, van der Hoeven JG, Pickkers P:
Crew Resource Management in the Intensive Care Unit: a prospective 3-year cohort study
Acta Anaesth Scand 2015; Volume 59, Issue 10 Pages 1319–1329

Haerkens MHTM, Lorraine CJ, Oud TC, Pickkers P, van der Hoeven JG:
Implementation Challenges of Crew Resource Management
J ICU Management & Practice 2016; 16(2):88; 90-91.

Haerkens MHTM, van Leeuwen W, Sexton JB, Pickkers P, van der Hoeven JG:
Validation of the Dutch language version of the Safety Attitudes Questionnaire (SAQ-NL).
BMC Health Serv Res 2016; 16:385

Haerkens MHTM, Noe PM, Kox M, van der Hoeven JG, Pickkers P:
Crew Resource Management in the Trauma Room: a prospective three-year cohort study
Provisionally accepted for publication in Eur J Emerg Med

Haerkens MHTM, van Leeuwen W, Kox M, Pickkers P, van der Hoeven JG:
A Longitudinal Study on the Effect of Crew Resource Management on clinical Safety Climate
Submitted

National

Andeweg CS, Vingerhoedt NM, van Vugt AB, Haerkens MHTM:
Damage Control Surgery for polytraumatized patients.
Ned Tijdschr Geneeskd. 2006; 150(27)

Haerkens MHTM, Beekmann RTA, van den Elzen GJP, Lansbergen MDI, Berlijn DL:
Using the Aviation quality assurance model to improve Patient Safety in Dutch Hospitals.
Ned Tijdschr Geneeskd. 2009; 153:A563

Lange JF, Dekker-van Doorn CM, Haerkens MHTM, Klein J:
Hospital Safety Culture: without culture change just cosmetic surgery
Ned Tijdschr Geneeskd. 2011; 155:A2253

Haerkens MHTM, Simons R, Kuipers A:
Doctor, may I fly into space?
Ned Tijdschr Geneeskd. 2011; 155:A3904

Haerkens MHTM, Tan ECTH, Lely E:
Injured soldiers and their Quality of Life.
Ned Tijdschr Geneeskd. 2012; 156:A5360

Haerkens MHTM, Lemson J, van der Starre C, Daniels M:
Crew Resource Management and Safety Culture in paediatrics.
Tijdschr voor Kindergeneeskd 2014; 82(5), 179-183

Haerkens MHTM, Tan ECTH, Bleeker C, van der Hoeven JG:
What to do after a terrorist bombing? 15 tips.
Ned Tijdschr Geneeskd 2016; 160:D379

Book chapters

Tan ECTH, Haerkens MHTM:
Crew Resource Management.
Book Acute Healthcare 2014; Chapter 1.4.
ISBN: 9789035236233

Haerkens MHTM:
Team aspects of Patient Safety
Book Dutch Patient Safety Manual 2016; Part 5, Chapter 23.
ISBN: 9789058983060

8.3
Acknowledgements / Dankwoord

Geheel in de geest van het onderwerp is dit proefschrift het resultaat van multidisciplinaire samenwerking met zeer diverse professionals.

Mijn bijzondere dank gaat uit naar:

(Co) Promotores

Prof. dr. J.H. van der Hoeven

Hans, zonder jou was deze missie niet mogelijk geweest. Je niet aflatende steun, scherpe analyses en relativeringsvermogen waren essentieel bij het tot stand komen van dit proefschrift. Dank voor je onvoorwaardelijke vertrouwen. Nunc aut nunquam.

Prof. dr. P. Pickkers

Peter, bedankt voor je aanstekelijke enthousiasme, onuitputtelijke energie en altijd politiek correcte humor waarmee je - bijna - alle wetenschappelijke chicanes wist te relativeren.

Dr. M. Kox

Matthijs, iedere samenwerking met jou was bijzonder. Je volbloed onderzoekersbrein laat niet slechts beide computers op je bureau duizelen. Dank voor je inzet als co-promotor!

Manuscript committee

Prof. dr. J.D. Kerby

Prof. dr. G.P. Westert

Prof. dr. G.J. Scheffer

Dear members of the manuscript committee, thank you for your time and interest in my thesis.

Paranimfen

Dr. E.C.T.H. Tan

Beste Edward, onze vriendschap gaat terug tot de woeste studentenjaren. Van dispuutsgenoot tot chirurgische, MMT- en CRM-collega. Het geeft een goed gevoel dat jij een van mijn paranimfen bent.

Kapitein-vlieger W. van Leeuwen, MSc

Wouter, als mede Redskin verraste me je focus, doortastendheid en collegialiteit niet, maar je wetenschappelijke bijdrage… Cum Laude.

Collegae van 299 en 301 Squadron der Koninklijke Luchtmacht

Onze gezamenlijke jaren zal ik blijven koesteren. De kracht van "Een team, een taak" heb ik bij jullie mogen ervaren en vormde de basis voor dit proefschrift. Vi Ipsa Grati.

Team Wings of Care

Beste Syb, Tames, Chris, Michiel, Erik, Edward, Twiggy, Wouter, Jacob en Gwen, jullie vriendschap, inzet en volharding hebben onze CRM-cultuurinterventies mogelijk gemaakt. En daarmee dit proefschrift. Dank!!

Prof. dr. R.J.A. Goris

Beste Jan, jij was de rode draad in mijn opleiding tot chirurg. Jouw visie heeft mijn toch ietwat ongebruikelijke loopbaan ruimte gegeven.

Dr. F.A.A.M. Croiset van Uchelen

Fred, jouw operatieve vaardigheden, (op)leiderschap, collegialiteit en humor hebben mijn perifere chirurgische opleidingsperiode waardevol gemaakt.

Prof. dr. W.J.M. Spaan

Beste Willy, onze discussies over vele, al dan niet bestuurlijke, aspecten van patientveiligheid waren een verrijking. Ik heb nimmer een meer betrokken ziekenhuisbestuurder ontmoet.

Drs. W.M. Schellekens

Beste Wim, ik heb steeds kunnen rekenen op je immer kritische en zuivere advies, hartelijk dank daarvoor.

Generaal-Majoor b.d. R. Nypels

Beste Rob, jij stond aan de basis van mijn militaire keuze. Gelukkig stopte jouw betrokkenheid niet na mijn actieve dienstperiode en heb je het tot stand komen van dit proefschrift nauw gevolgd.

Generaal b.d. D.L Berlijn

Dick, dank voor alle raad en vertrouwen. Als alle leiders in de zorg jouw voorbeeld toch eens zouden durven volgen: leading people by walking behind them. Anytime, anywhere.

Majoor b.d. G.J.P. van den Elzen

Waarde Guus, onze immer licht entropische gesprekken heb ik zo lang we elkaar kennen als motiverend en waardevol ervaren. Evenals je vriendschap.

Pa,
dank voor alles dat je altijd met, en helaas sinds twee jaar zonder, ma voor ons hebt gedaan. Ik beloof de komende periode meer tijd samen te hebben.

Lieve Hortence,
al 33 jaar ben je mijn allerliefste maatje en relativerende klankbord. Pas met jou krijgt alles zin.

Laika,
als jij toch kon praten…

8.4
Curriculum Vitae

Curriculum Vitae

Marck Haerkens was born on June 26, 1962 in Eindhoven, the Netherlands.

After graduating from the Augustinianum Eindhoven in 1982 he was admitted into Radboud University Medical School in Nijmegen. During his study he became a mentor for new students, founded the Medical Society SO.DA. NO.GO. and worked in Cape Town (South-Africa) and Cairo (Egypt) as an exchange student.

Marck joined the Netherlands armed forces in 1989. After serving as a battalion physician with 103 Recon Batt in Seedorf (Germany) he became a flight surgeon with the Royal Netherlands Air Force (RNLAF) and was stationed at Deelen and Volkel Air Force Base (AFB).

Already a glider pilot, Marck's love for flying convinced the RNLAF to allow him into flight training. This resulted in a full Military Aviator license. After earning his wings he gained type ratings on the Bölkow Bo-105cb light utility and AH-64D Apache attack helicopters with 299 and 301 Squadron at Gilze-Rijen AFB.

The combined qualification as physician and military aviator, called "pilot-physician", allowed him to appreciate the parallels between the medical world and the aviation domain.

In 1995 Marck started his surgical residency. After training in Radboudumc and Maxima Medical Center he graduated as a surgeon in 2001. His exposure to trauma care started in San Antonio, Texas (USA) at United States Air Force (level 1 trauma centre) Wilford Hall Medical Centre, and later grew as a

consultant trauma surgeon at Radboud umc and Jeroen Bosch Hospital, Helicopter Emergency Medical Service (HEMS)-physician with the Lifeliner 3-team (while initially responsible for HEMS flight operations), and during military deployments in Iraq and Afghanistan. Marck became a qualified instructor on several international trauma and critical care courses (BATLS®, APLS®, DSTC®, DSTS®).

In May 2009 he retired from the RNLAF as a full Colonel, remaining a reserve officer to date. Marck founded the organization Wings of Care (WoC) to further enhance safety and efficacy of clinical patient care and raise Human Factors awareness in multiple critical domains. With his WoC-team he provides lectures, training and coaching for healthcare professionals, leaders and organizations.

Marck has been awarded the General Snijders Honours' Diploma for his combined work in Aviation and Medicine in 2009 and, together with the Department of Intensive Care at Radboud umc, the 2013 Dutch Health Inspectorate's National Patient Safety Award.

He lives in the village of Vught with his wife Hortence Haerkens-Arends, cardiologist, and their German Shorthaired Pointer Laika.

8.5
Stellingen / Propositions

STELLINGEN

behorende bij het proefschrift
Human Factors and Team Performance

1. Het veiligheidsklimaat van een afdeling is te meten. (dit proefschrift)

2. Artsen schatten het veiligheidsklimaat op een afdeling hoger in dan verpleegkundigen. (dit proefschrift)

3. Slechts 1 op de 7 medische professionals voelt zich gesteund door het ziekenhuismanagement. (dit proefschrift)

4. Crew Resource Management (CRM) is geassocieerd met een verbeterd veiligheidsklimaat op zowel de Intensive Care (IC) als Spoedeisende Hulp. (dit proefschrift)

5. Integratie van scenario training in een CRM-cultuurinterventie is geassocieerd met een verbeterd veiligheidsklimaat. (dit proefschrift)

6. CRM is geassocieerd met een afname van ernstige complicaties en een reductie van mortaliteit op de IC. (dit proefschrift)

7. De zorg is een uniek domein, waar klimaatverandering juist wenselijk is.

8. Het feit dat op iedere promotie-uitnodiging achter de aanvangstijd "precies" staat, geeft aan dat academische punctualiteit niet vanzelfsprekend is.

9. De missie van militaire vliegers, traumachirurgen en promovendi: het oncontroleerbare controleren.

10. You want a surgical team that faces each error, each mishap, straight up, names it, and takes steps to prevent its recurrence.
    Francis D Moore

11. Don't ask what the world needs. Ask what makes you come alive, and go do it. Because what the world needs is people who have come alive.
    Howard Truman

12. He will win whose army is animated by the spirit throughout all its ranks. *Sun Tzu, The Art of War*

PROPOSITIONS

accompanying the thesis
Human Factors and Team Performance

1. A department's safety climate is measurable. (this thesis)

2. Doctors perceive their department's safety climate better than nurses. (this thesis)

3. Only 1 out of 7 clinical professionals feels supported by their hospital management. (this thesis)

4. CRM is associated with an improved safety climate both on the Intensive Care Unit (ICU) and the Emergency Department. (this thesis)

5. Integration of simulation training into Crew Resource Management (CRM) implementation is associated with improvements in safety climate. (this thesis)

6. CRM is associated with a reduction in serious complications and a reduction in mortality at the ICU. (this thesis)

7. Healthcare is a unique domain where climate change is a good thing.

8. The fact that every invitation for a PhD thesis defense states the word "exactly" after the starting time indicates that academic punctuality is not self-evident.

9. The mission of military aviators, trauma surgeons and PhD candidates is to control the uncontrollable.

10. You want a surgical team that faces each error, each mishap, straight up, names it, and takes steps to prevent its recurrence.
    Francis D Moore

11. Don't ask what the world needs. Ask what makes you come alive, and go do it. Because what the world needs is people who have come alive.
    Howard Truman

12. He will win whose army is animated by the spirit throughout all its ranks. *Sun Tzu, The Art of War*